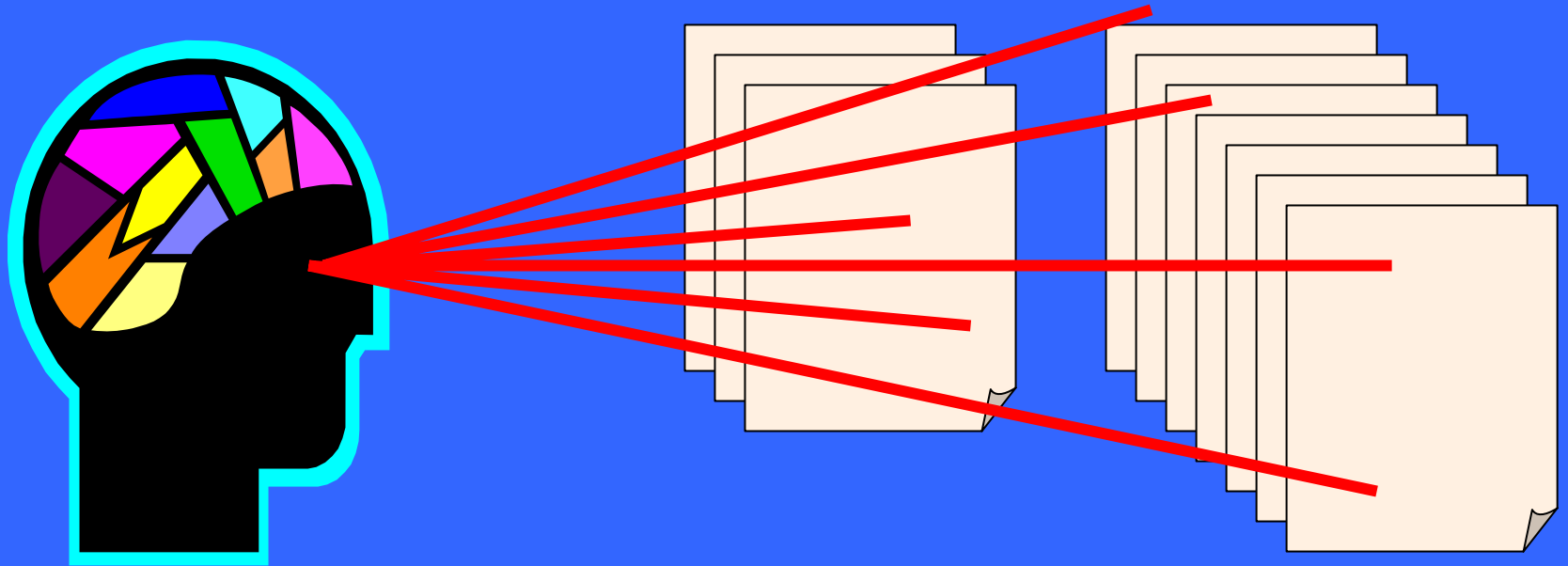


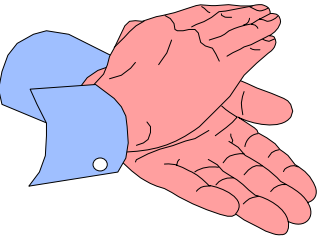
Mandatory Drug Risk Information: How much information is too much?



Ruth S. Day / Duke University

FDA Public Hearing / Medication Guides
Washington, DC -- June 12, 2007

ACKNOWLEDGEMENTS



Research Assistants

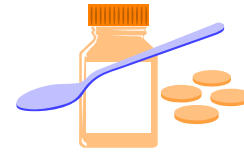
Daniel C. Howard
Sarah Bland

Funded by AHRQ* and FDA

*Duke CERTs grant# HS101548

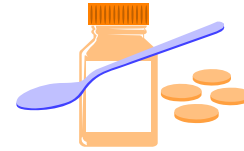
QUESTION:

How do people understand risk information?



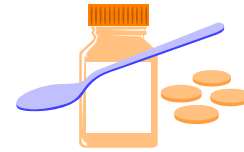
QUESTION:

How do people understand risk information?



ANSWER: With difficulty!

QUESTION:



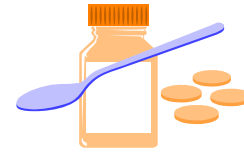
How do people understand risk information?

ANSWER: With difficulty!

WHY:

- Heavy information load
- Complex/technical information
- etc.

QUESTION:



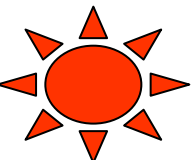
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ANSWER: With difficulty!

WHY:

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- etc.

--**Cognitive IN-Accessibility**

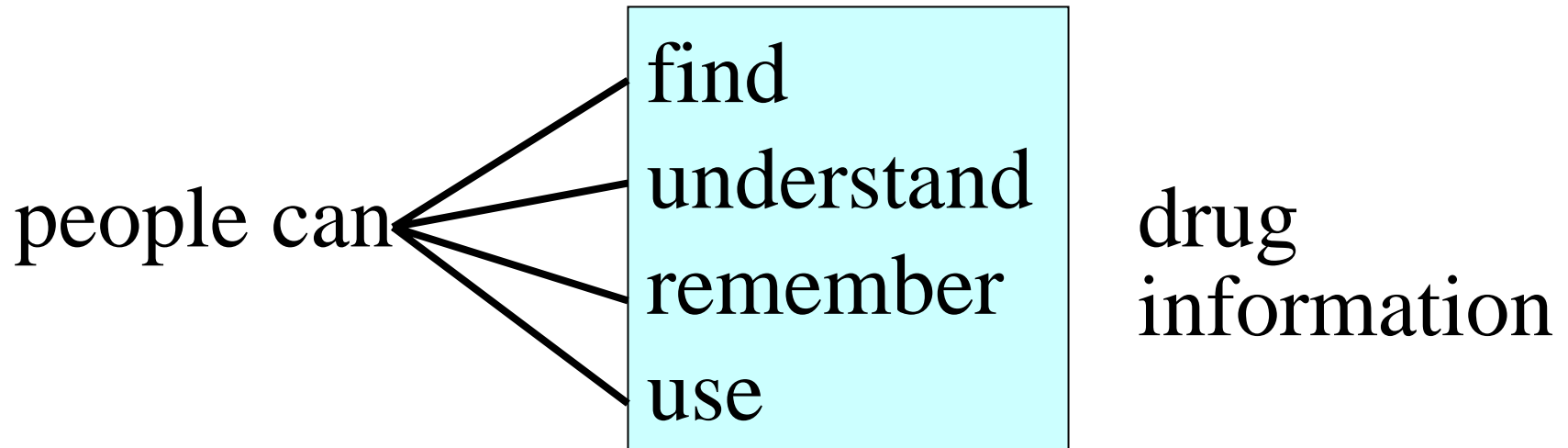


Cognitive Accessibility

The ease with which

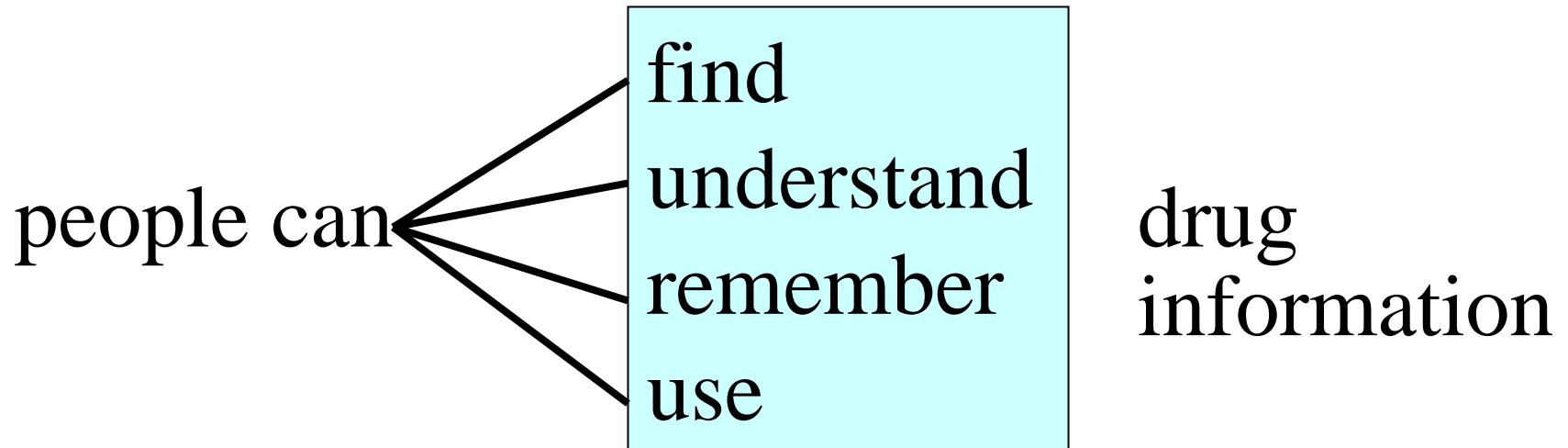
Cognitive Accessibility

The ease with which



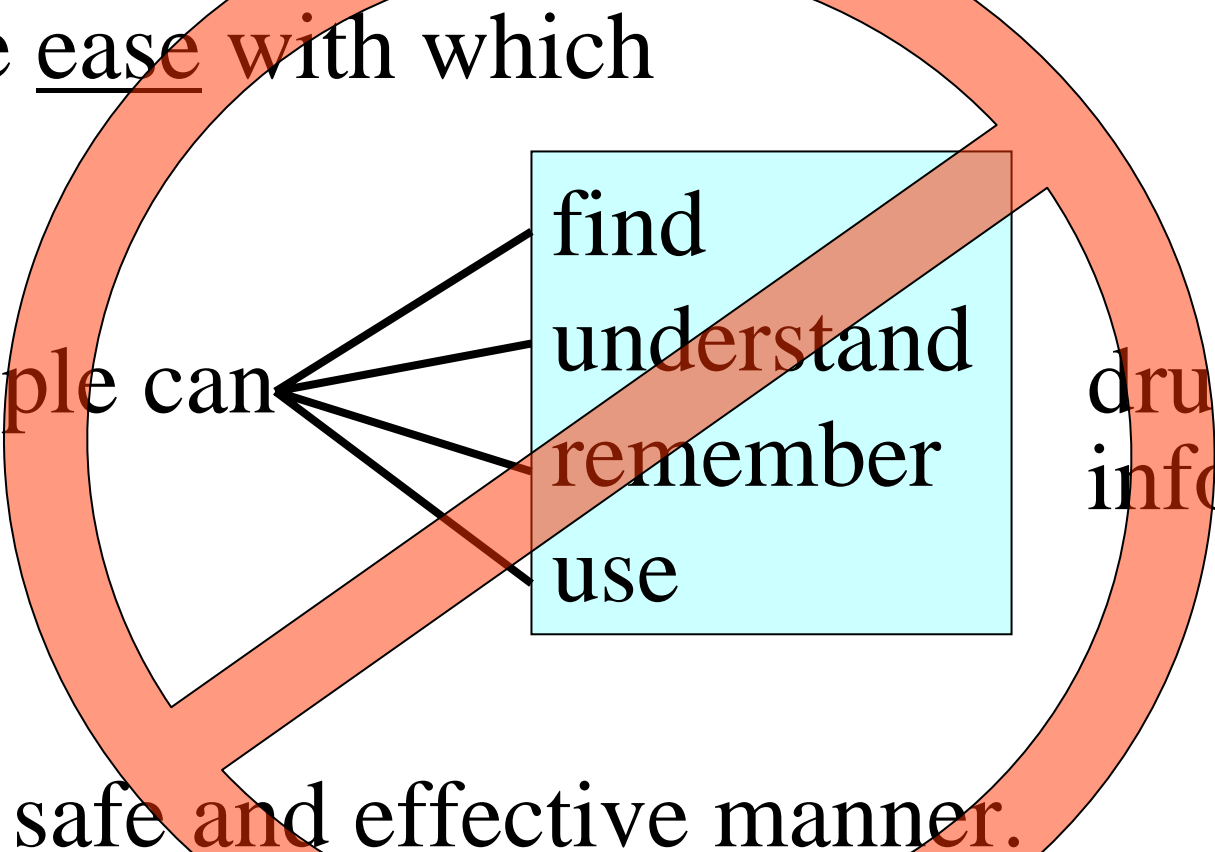
Cognitive Accessibility

The ease with which



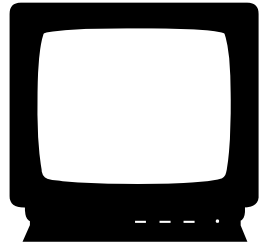
in a safe and effective manner.

Cognitive **IN**-Accessibility

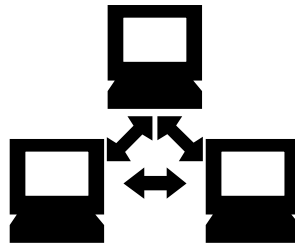
The ease with which
people can 
drug
information
in a safe and effective manner.

TYPES of INFORMATION

TV Ads



Internet

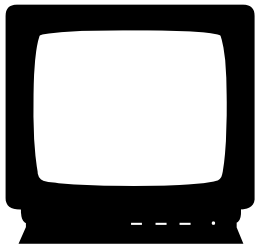


Hardcopy

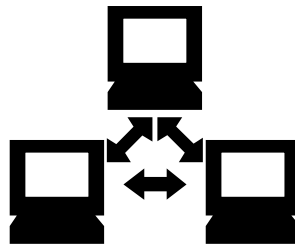


TYPES of INFORMATION

TV Ads



Internet



Hardcopy



Medication Guides

Professional Label

Patient Package Inserts

Consumer Med.Info (CMI)

(etc.)

BASIC APPROACH

```
graph TD; A["BASIC APPROACH"] --> B["Cognitive Analyses"]; A --> C["Enhanced Displays"]; A --> D["Cognitive Experiments"];
```

**Cognitive
Analyses**

**Enhanced
Displays**

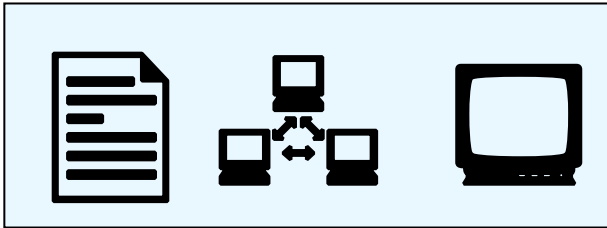
**Cognitive
Experiments**

BASIC APPROACH

**Cognitive
Analyses**

**Enhanced
Displays**

**Cognitive
Experiments**

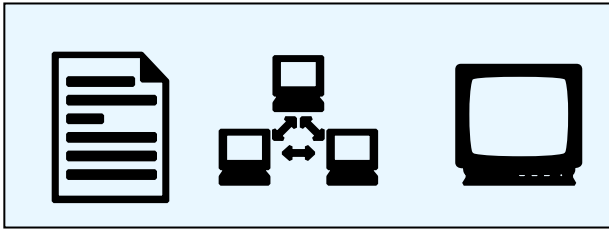


--Obtain quantitative
measures

--Calculate
“cognitive accessibility”

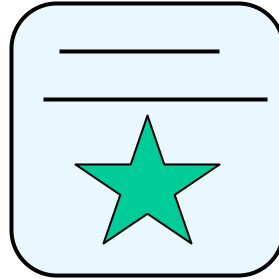
BASIC APPROACH

Cognitive Analyses



- Obtain quantitative measures
- Calculate “cognitive accessibility”

Enhanced Displays

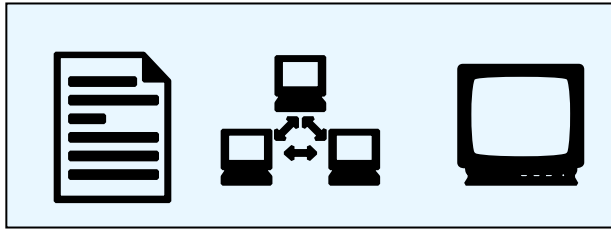


- Same info
- Based on cognitive principles

Cognitive Experiments

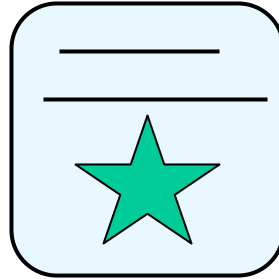
BASIC APPROACH

Cognitive Analyses



- Obtain quantitative measures
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Enhanced Displays



- Same info
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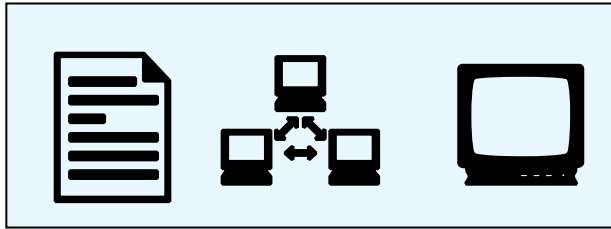
Cognitive Experiments

Test effects on:

- Attention
- Comprehension
- Memory
- Problem Solving
- Decision Making
- Behavior

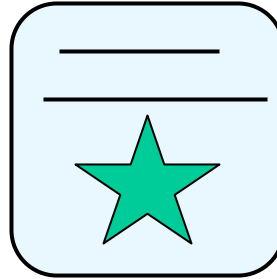
BASIC APPROACH

Cognitive Analyses



- Obtain quantitative measures
- Calculate “cognitive accessibility”

Enhanced Displays



- Same info
- Based on cognitive principles

Cognitive Experiments

Test effects on:

- Attention
- Comprehension
- Memory
- Problem Solving
- Decision Making
- Behavior

Health Outcomes

COGNITIVE PRINCIPLES

Information Load

Chunking

Coding

Representation

**Visual
Distinctiveness**

Location

Readability

Prior Knowledge

Comprehension

Attention

Cognitive Task

Metacognition

COGNITIVE PRINCIPLES

Information Load

Chunking

Coding

Representation

**Visual
Distinctiveness**

Location

Readability

Prior Knowledge

Comprehension

Attention

Cognitive Task

Metacognition

Project Goals

Project Goals

1) Evaluate current versions

- cognitive accessibility
- benefits, risks, etc.

2) Determine

- what is working well?
- what is not?

Project Goals

1) Evaluate current versions

- cognitive accessibility
- benefits, risks, etc.

2) Determine

- what is working well?
- what is not?

3) Design alternative representations

- to enhance cognitive accessibility

Project Goals

4) Recruit participants

--relevant health status

5) Test effects of original & enhanced representations on:

--comprehension

--memory

--problem solving

6) Improve performance?

Documents

Mandatory Drug Information

Documents

Mandatory Drug Information

isotretinoin

Documents

Mandatory Drug Information

isotretinoin

ACCUTANE

Medication
Guide

Documents

Mandatory Drug Information

estrogen

isotretinoin

ACCUTANE

Medication
Guide

Documents

Mandatory Drug Information

estrogen

PREMARIN

Mandatory
Patient
Package
Insert

isotretinoin

ACCUTANE

Medication
Guide

Documents

Mandatory Drug Information

estrogen

PREMARIN

Mandatory
Patient
Package
Insert

isotretinoin

ACCUTANE

Medication
Guide



PROJECTS

**Phone
Survey**



CERTs

PROJECTS

**Phone
Survey**



CERTs

**Laboratory
Experiments**



Medical Cognition Lab

PROJECTS

Phone
Survey



CERTs

Laboratory
Experiments



Medical Cognition Lab

Load

Load

How much is too much?

Load

How much is too much?

**Information
Load**

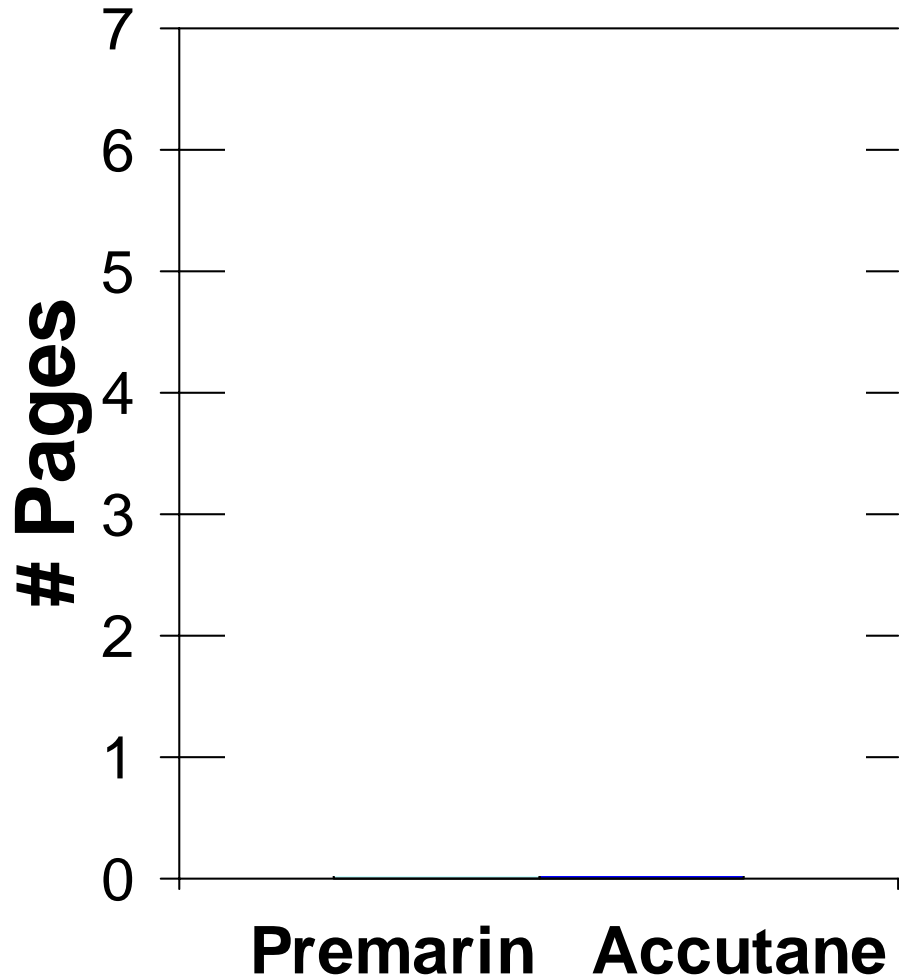
Load

How much is too much?

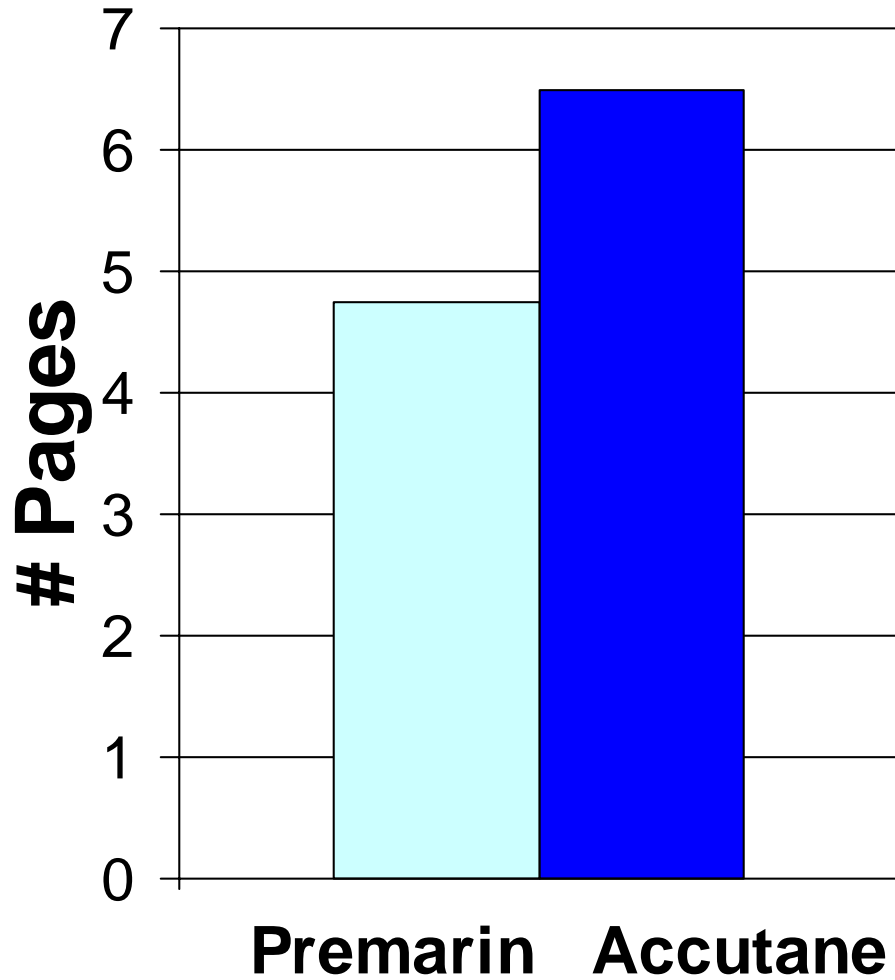
Information
Load

Cognitive
Load

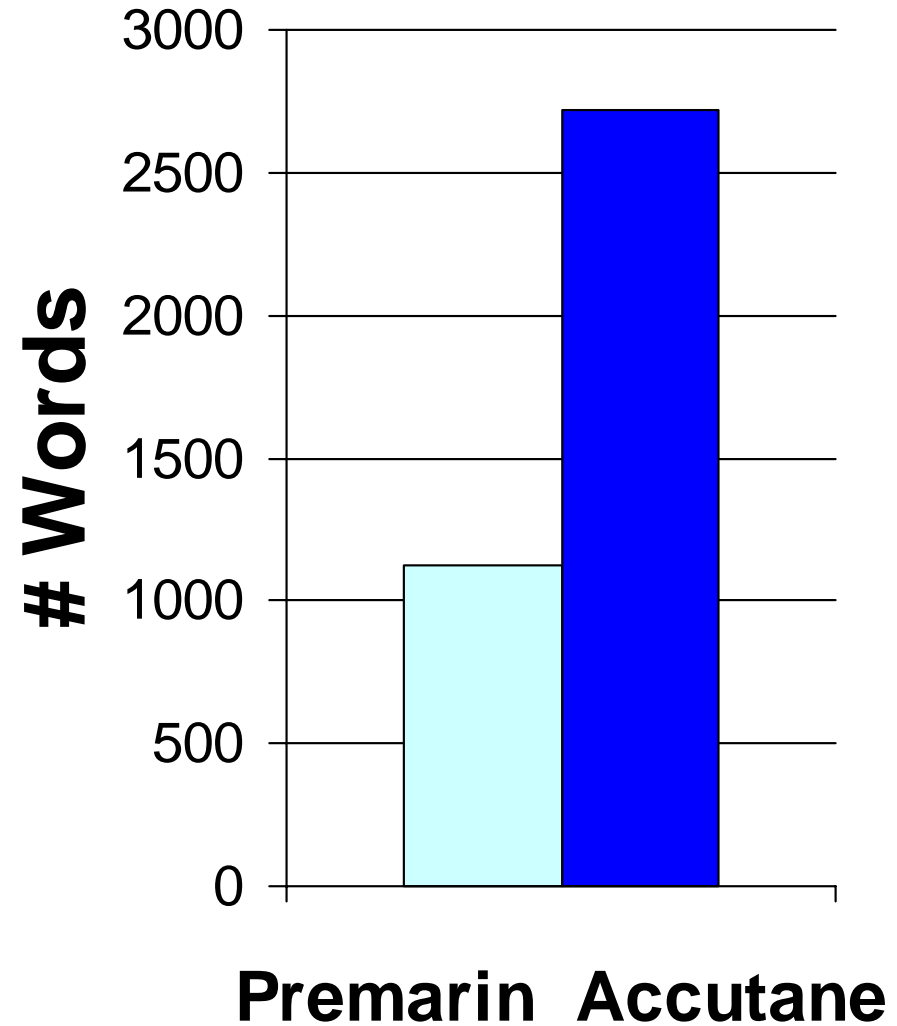
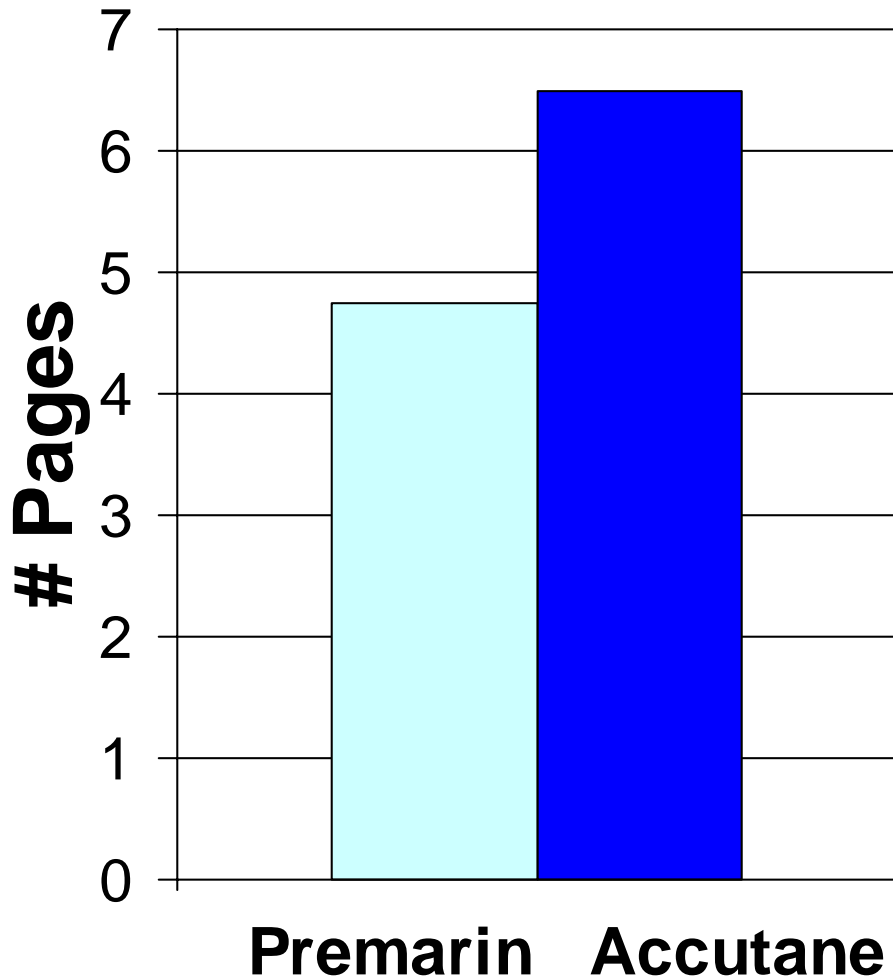
Information Load



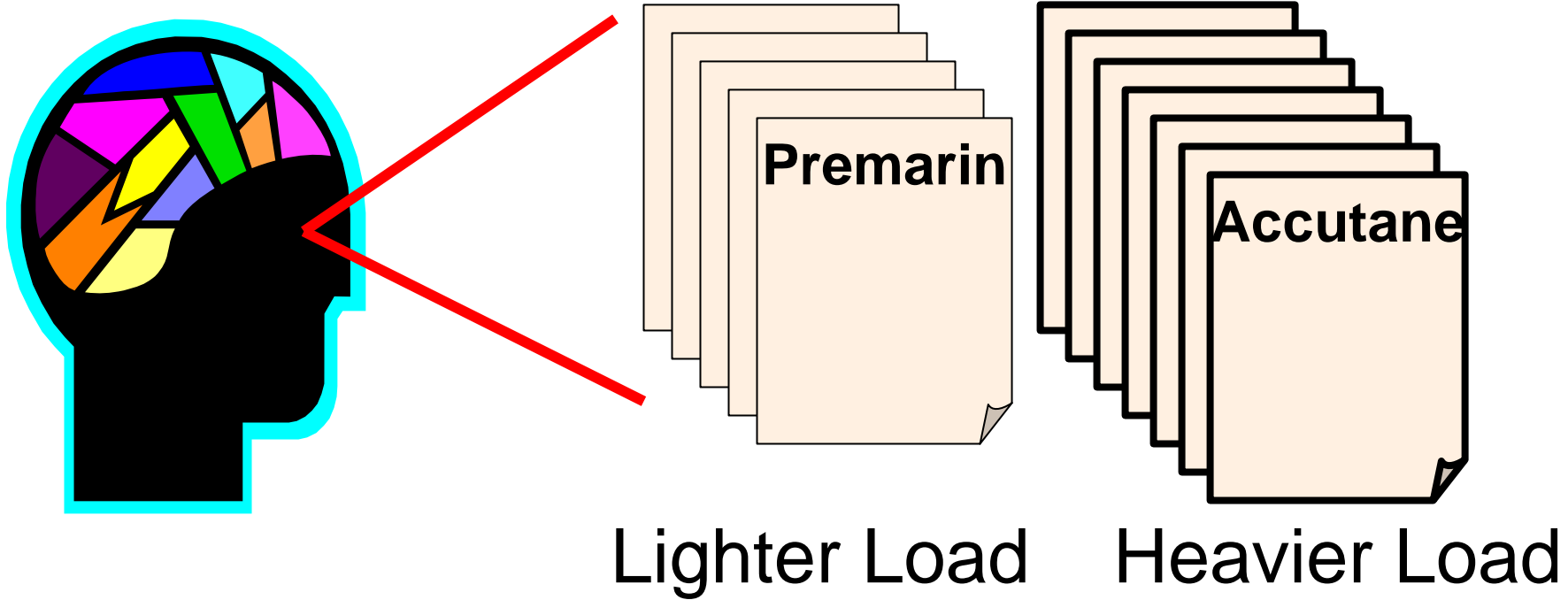
Information Load



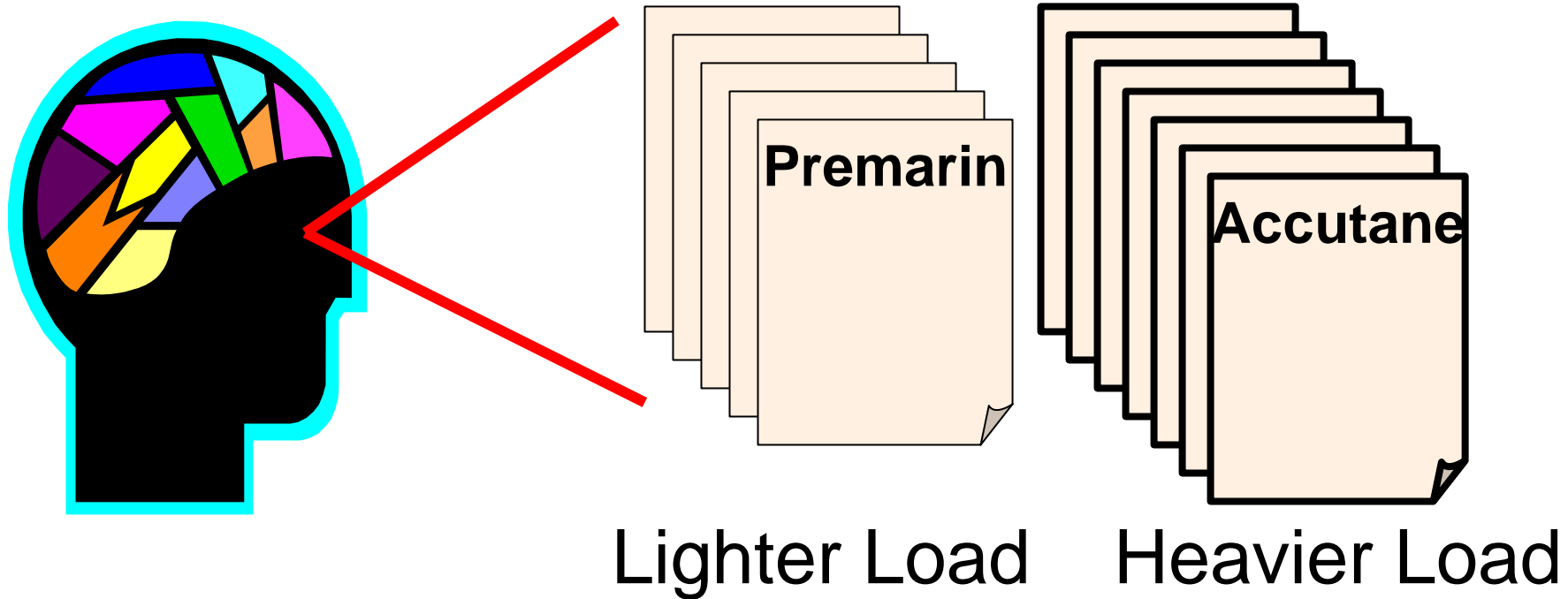
Information Load



Information Load



Information Load



Prediction

Performance on Premarin > Accutane

Participants

Participants

Selection Criteria

Premarin

- female
- age 40 or older
- interested in
information about
hormone replacement

Participants

Selection Criteria

Premarin

--female

--age 40 or older

--interested in
information about
hormone replacement

Accutane

--[]

--age 18 or older

--interested in
information about
acne treatments

Participants

Selection Criteria

Premarin

- female
- age 40 or older
- interested in information about hormone replacement

N = 78

Accutane

- []
- age 18 or older
- interested in information about acne treatments

N = 78

Participants

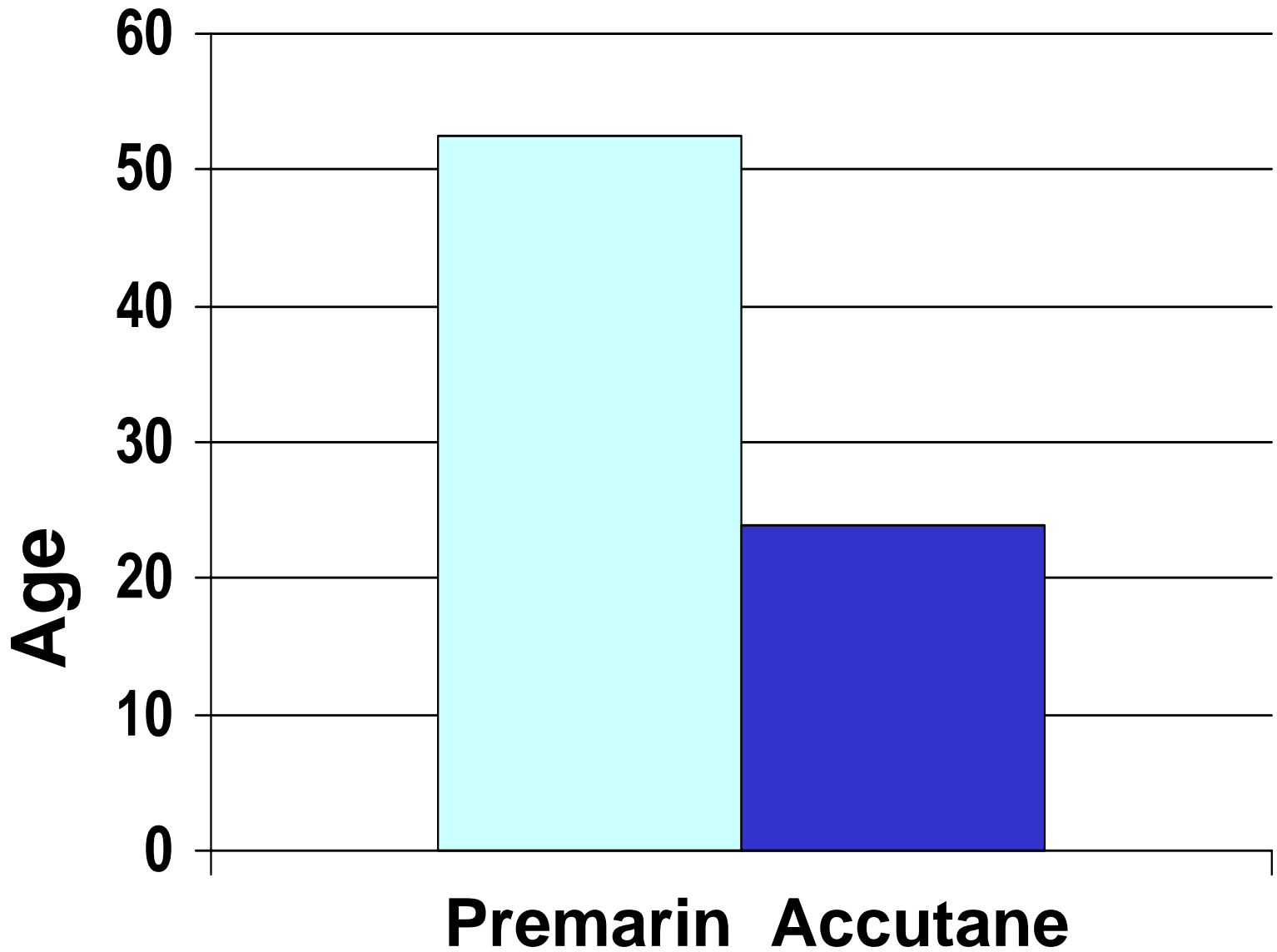
--# participants = 156

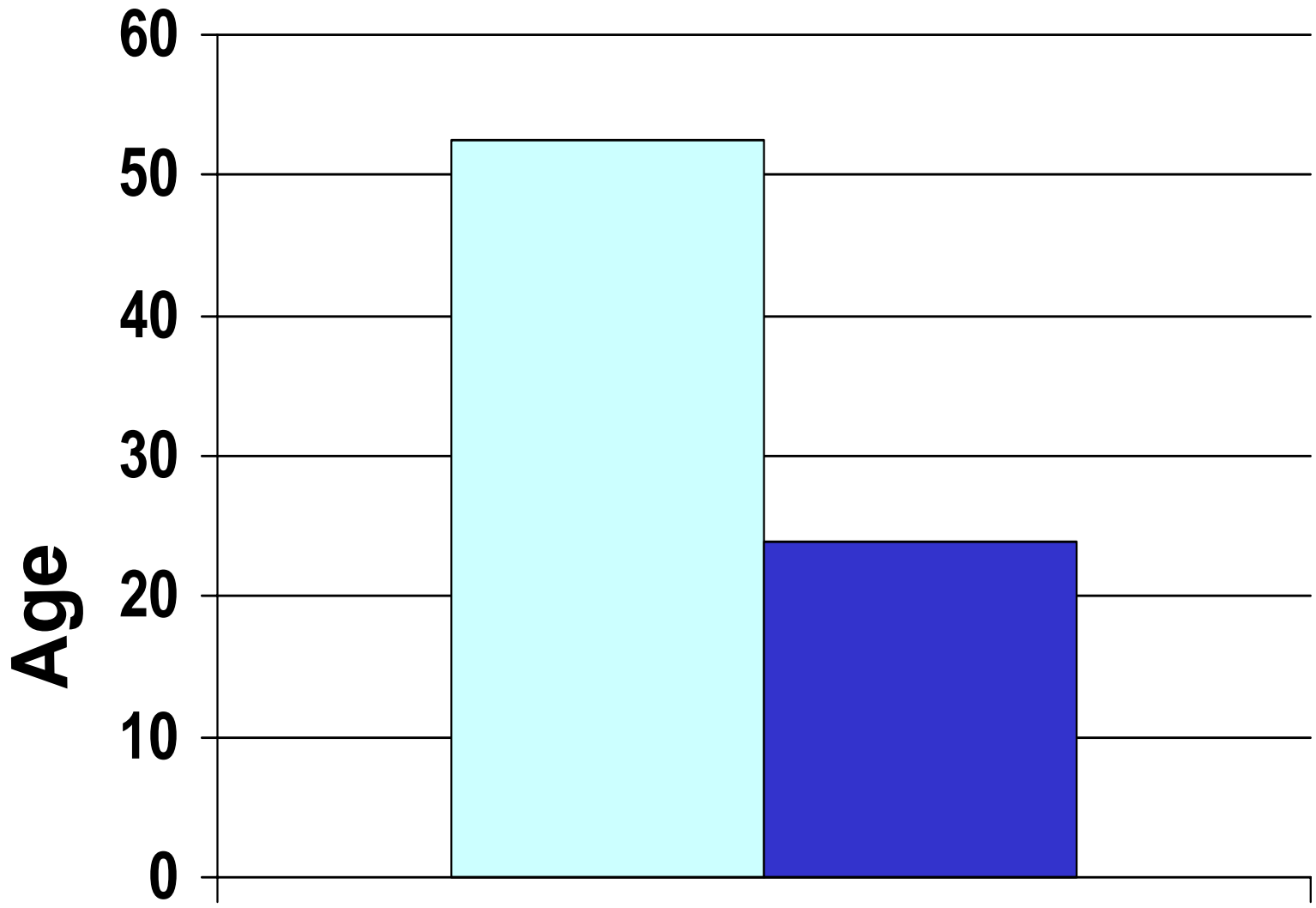
--multiple experiments

--multiple measures

TOTAL #

Observations > 87,000





Premarin Accutane

% Female = 100% 68%

Basic Methods

Basic Methods

time



Study

Test

Basic Methods

time



Study

Test

**All
Content**

**Multiple
Tasks**

Sample results

Both Drugs

General Views

General Views

time

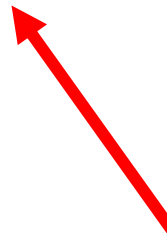


Study

Test

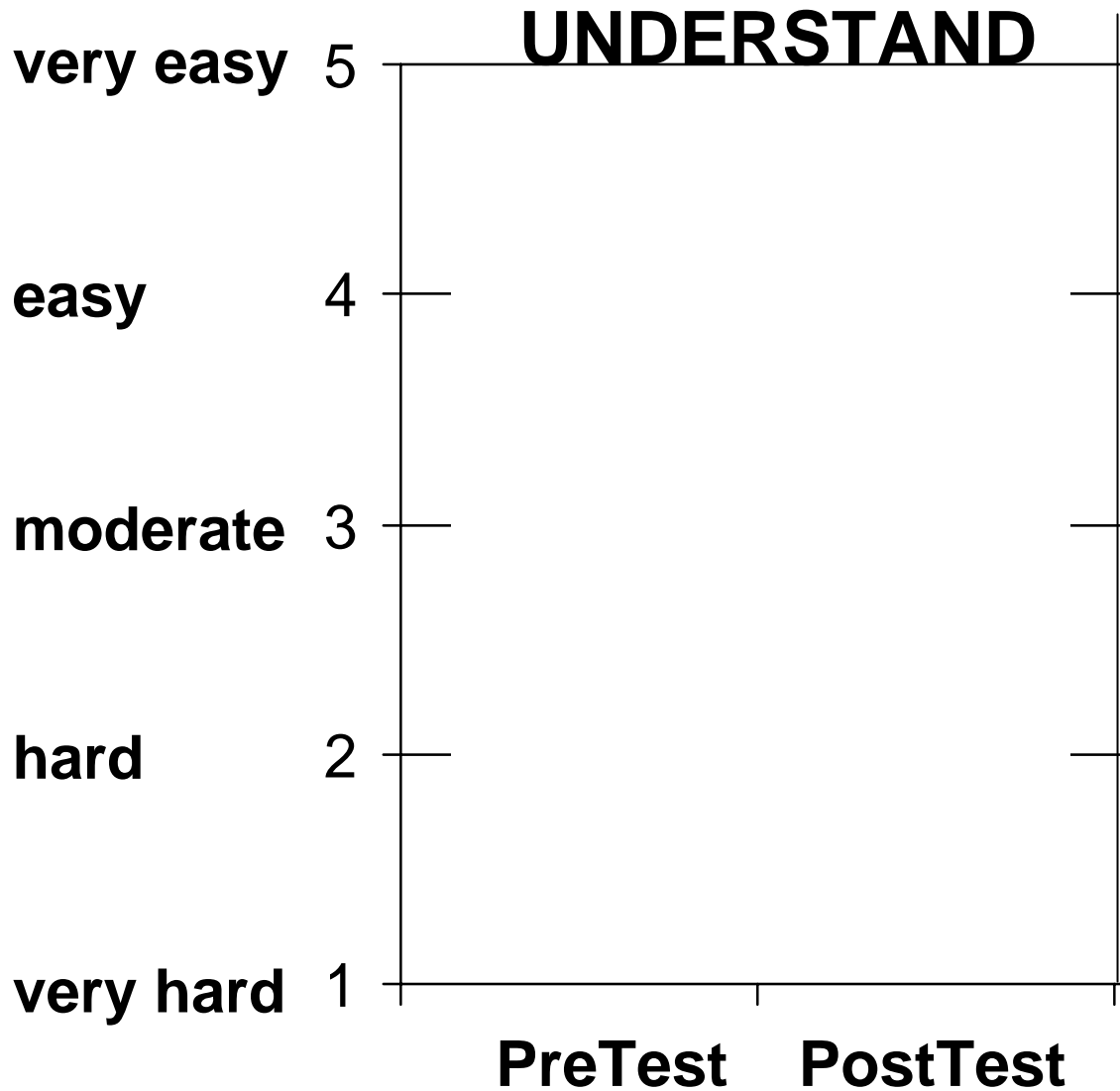
PreTest

PostTest

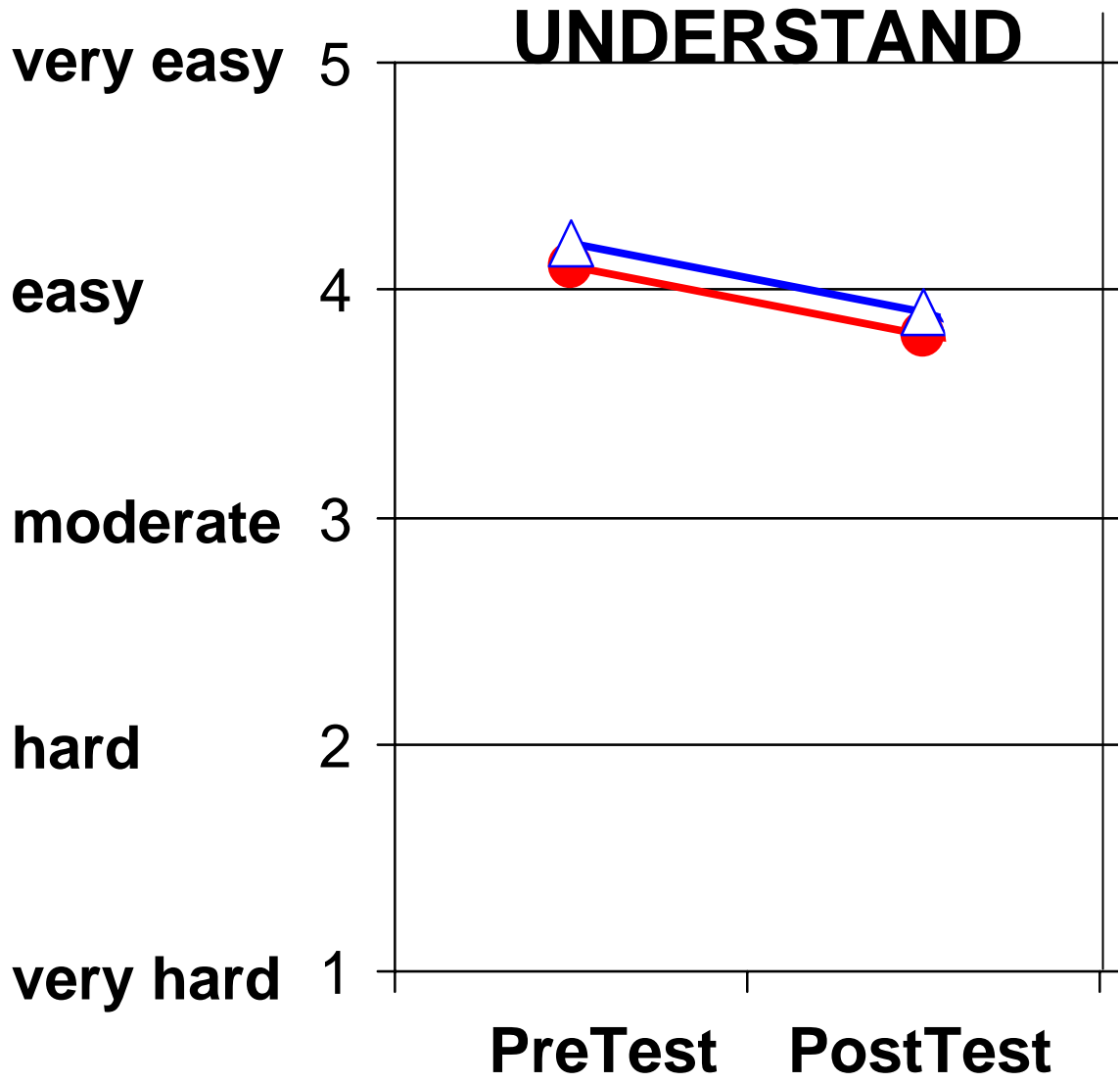
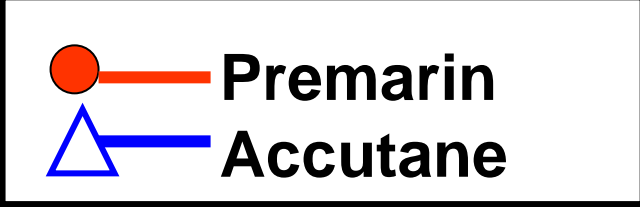


*“How easy was it to **understand** the information in the leaflet?”*

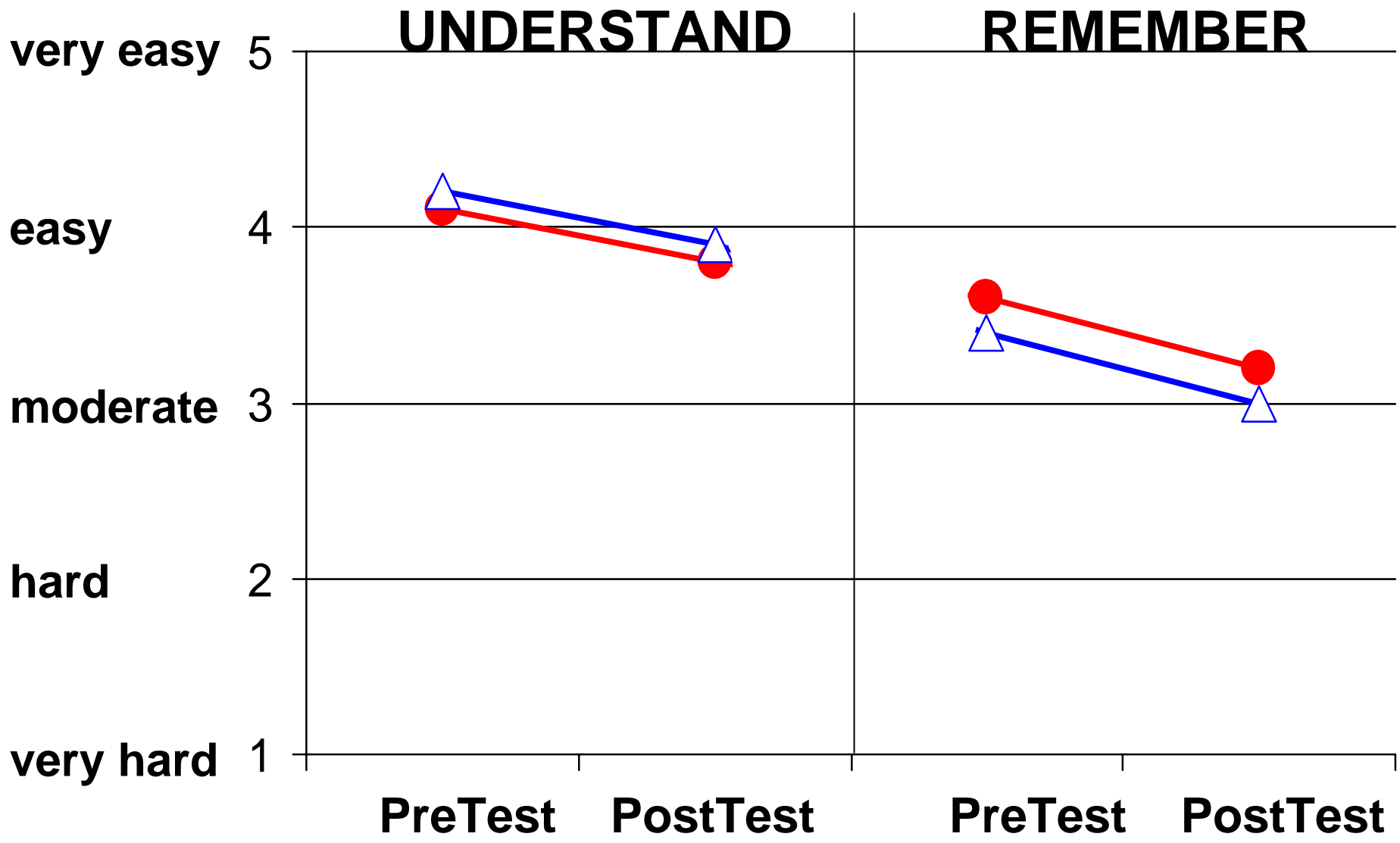
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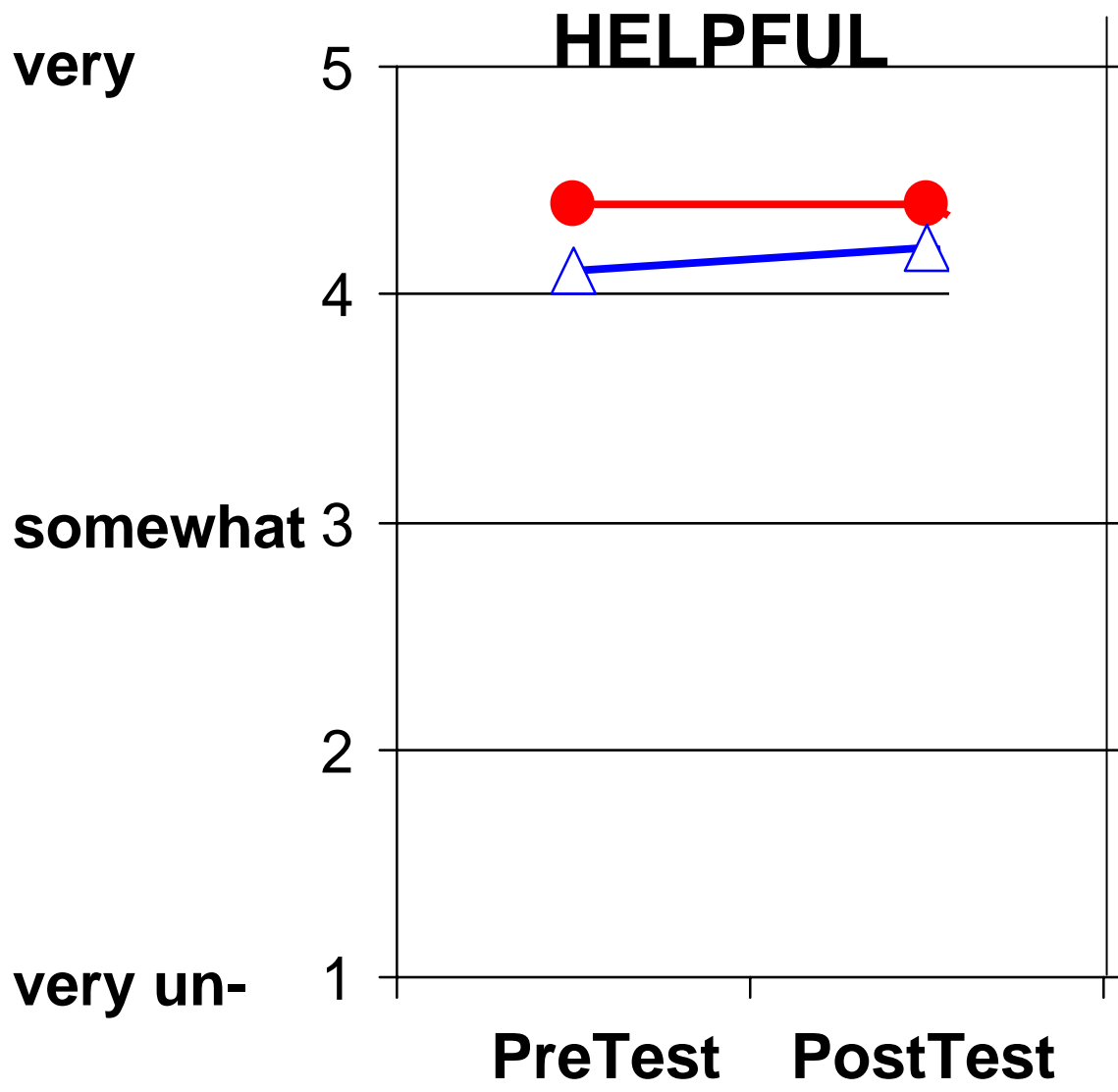
*“How easy was it to **understand** the information in the leaflet?”*



“How easy would it be to remember the information in the leaflet?”



“How *helpful* was the leaflet?”



General Views

Conclusions

- People overestimated how much they knew and understood after reading
- After testing, they realized they knew less than they thought

General Views

Conclusions

- People overestimated how much they knew and understood after reading
- After testing, they realized they knew less than they thought
- Nevertheless, still they found the documents “helpful”

Contraindications & Precautions

Contraindications & Precautions



“You should not start taking this medicine if you have certain conditions. What are these conditions?”

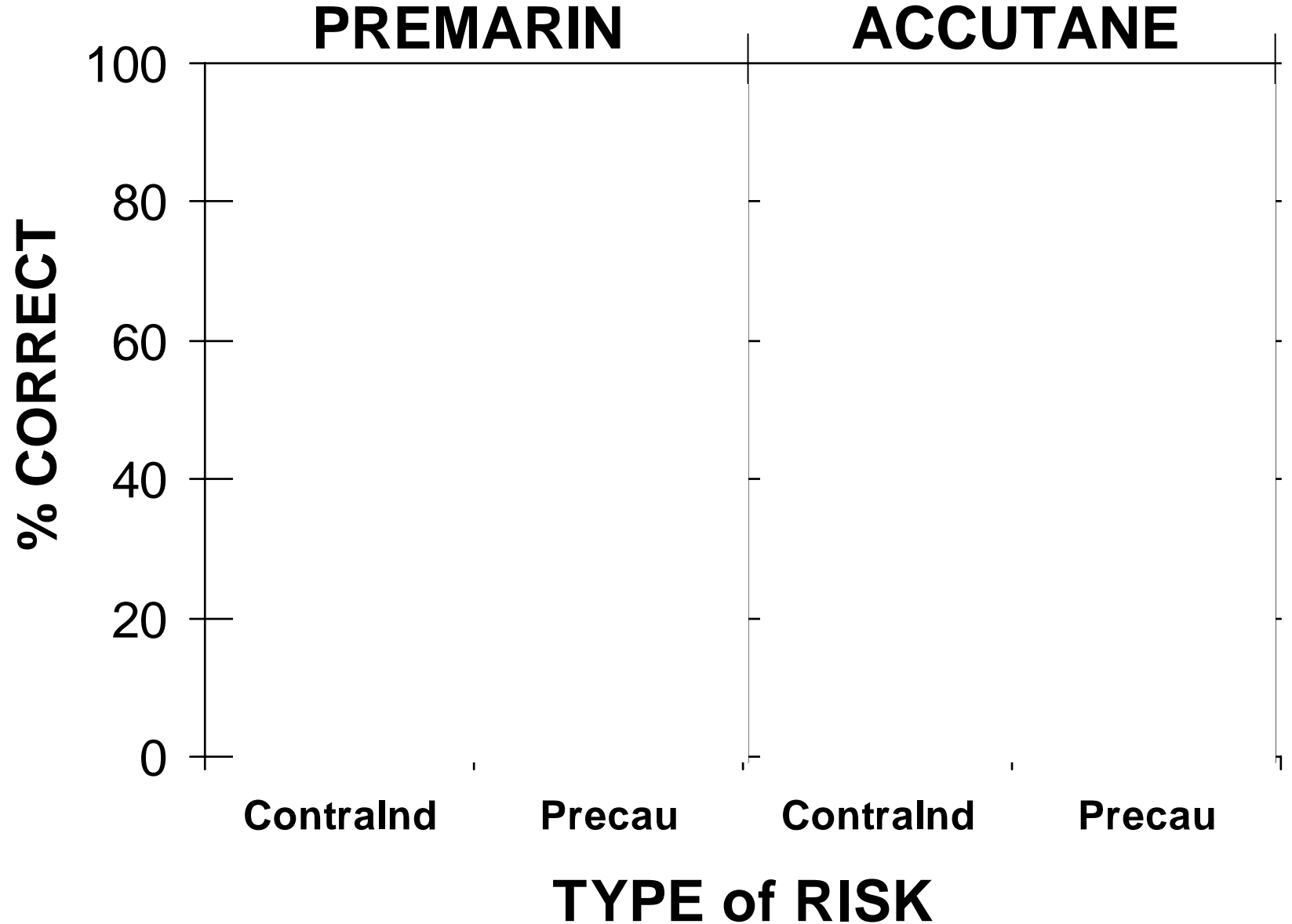
Contraindications & Precautions

```
graph TD; A[Contraindications & Precautions] --> B["You should not start taking this medicine if you have certain conditions. What are these conditions?"]; A --> C["What should you tell your healthcare provider before using this medicine?"]
```

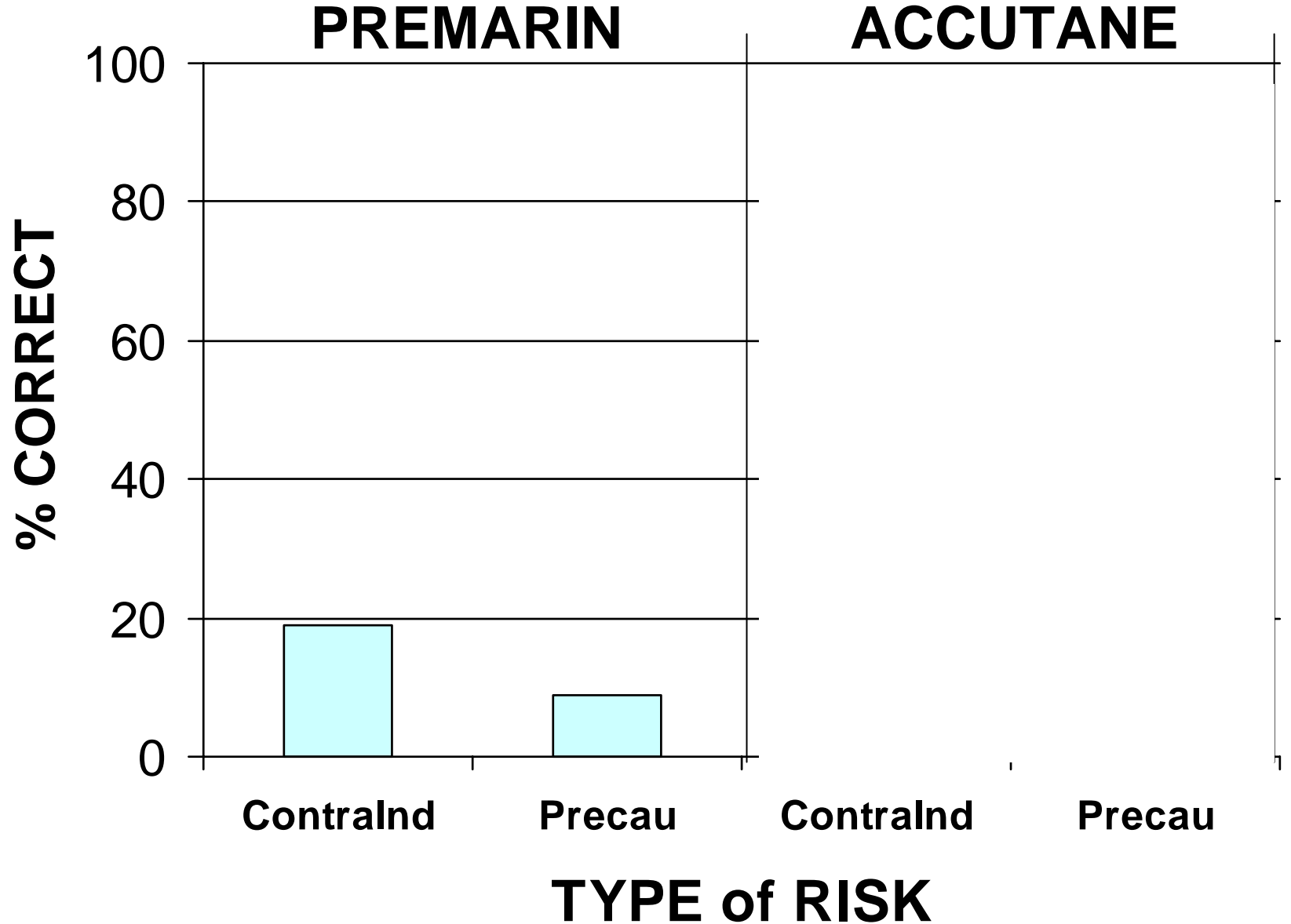
“You should not start taking this medicine if you have certain conditions. What are these conditions?”

“What should you tell your healthcare provider before using this medicine?”

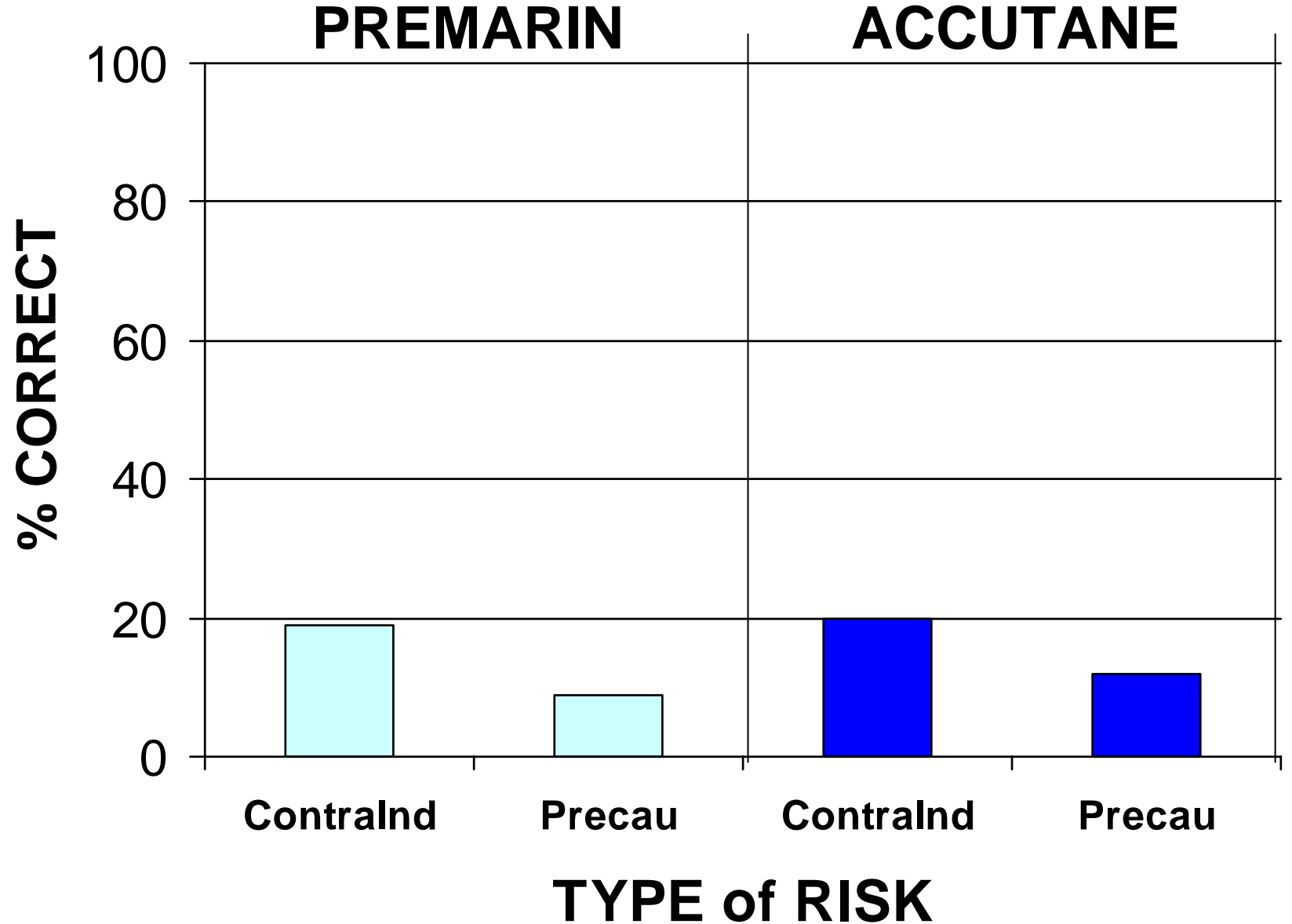
Contraindications & Precautions



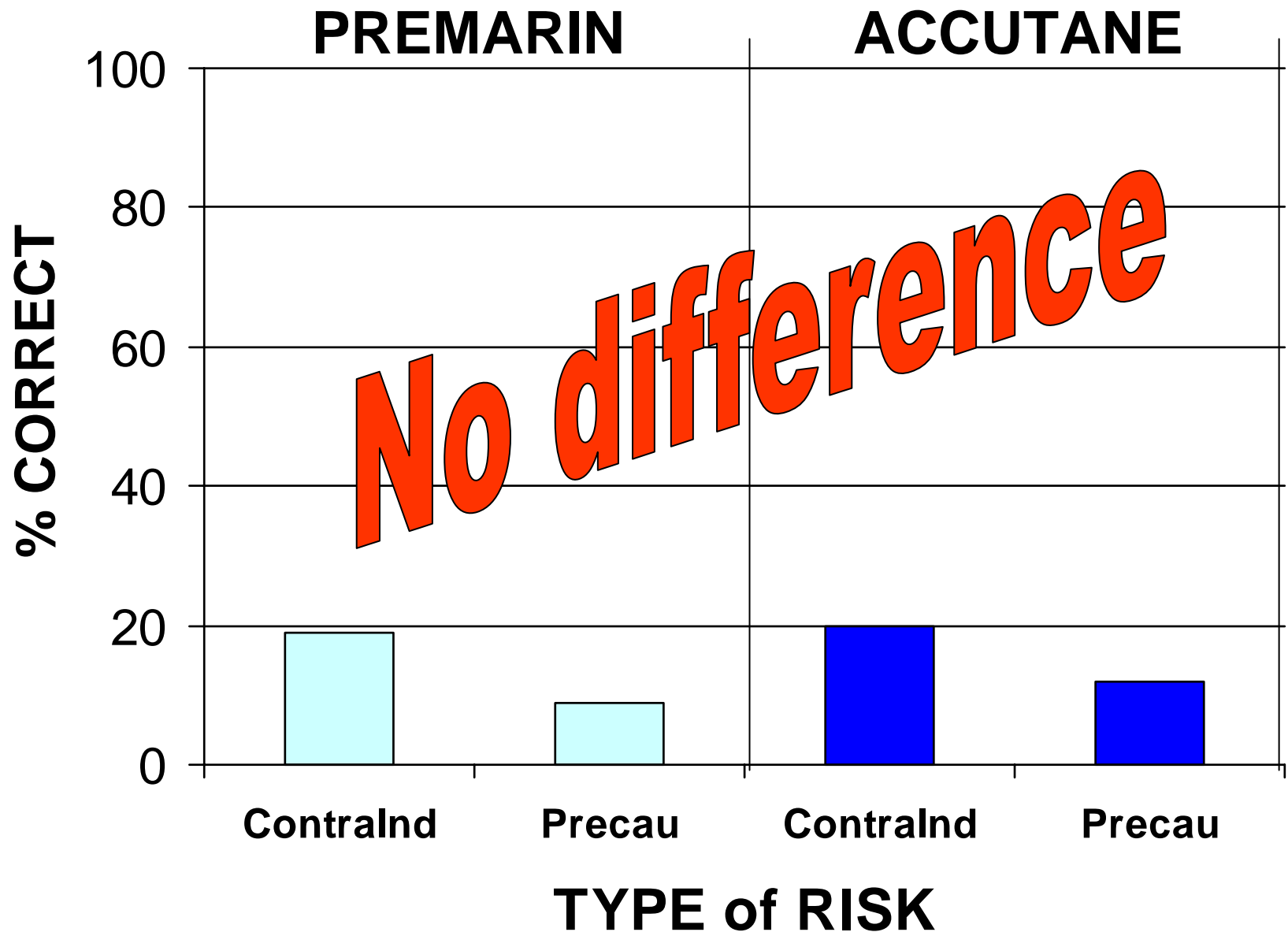
Contraindications & Precautions



Contraindications & Precautions



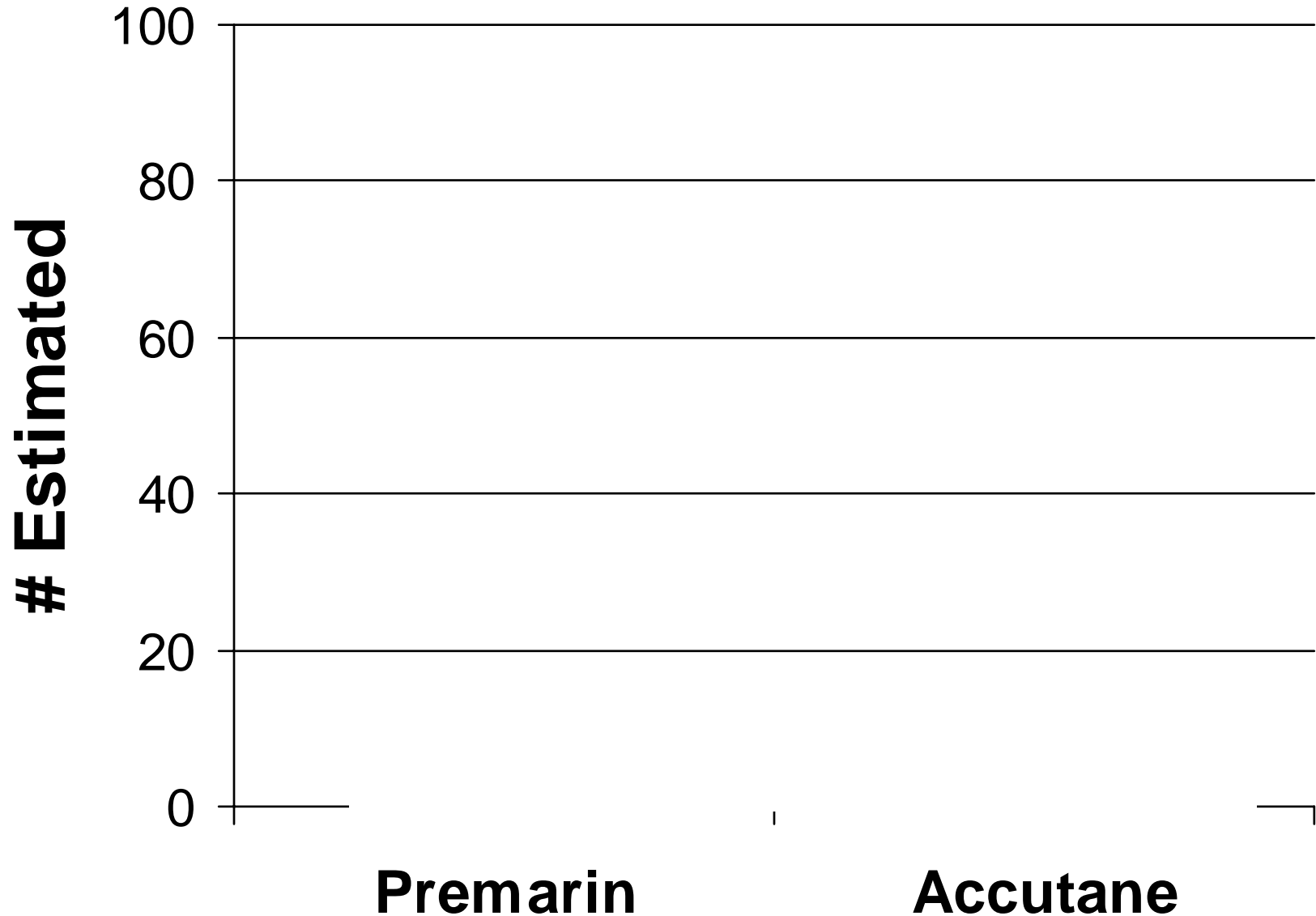
Contraindications & Precautions



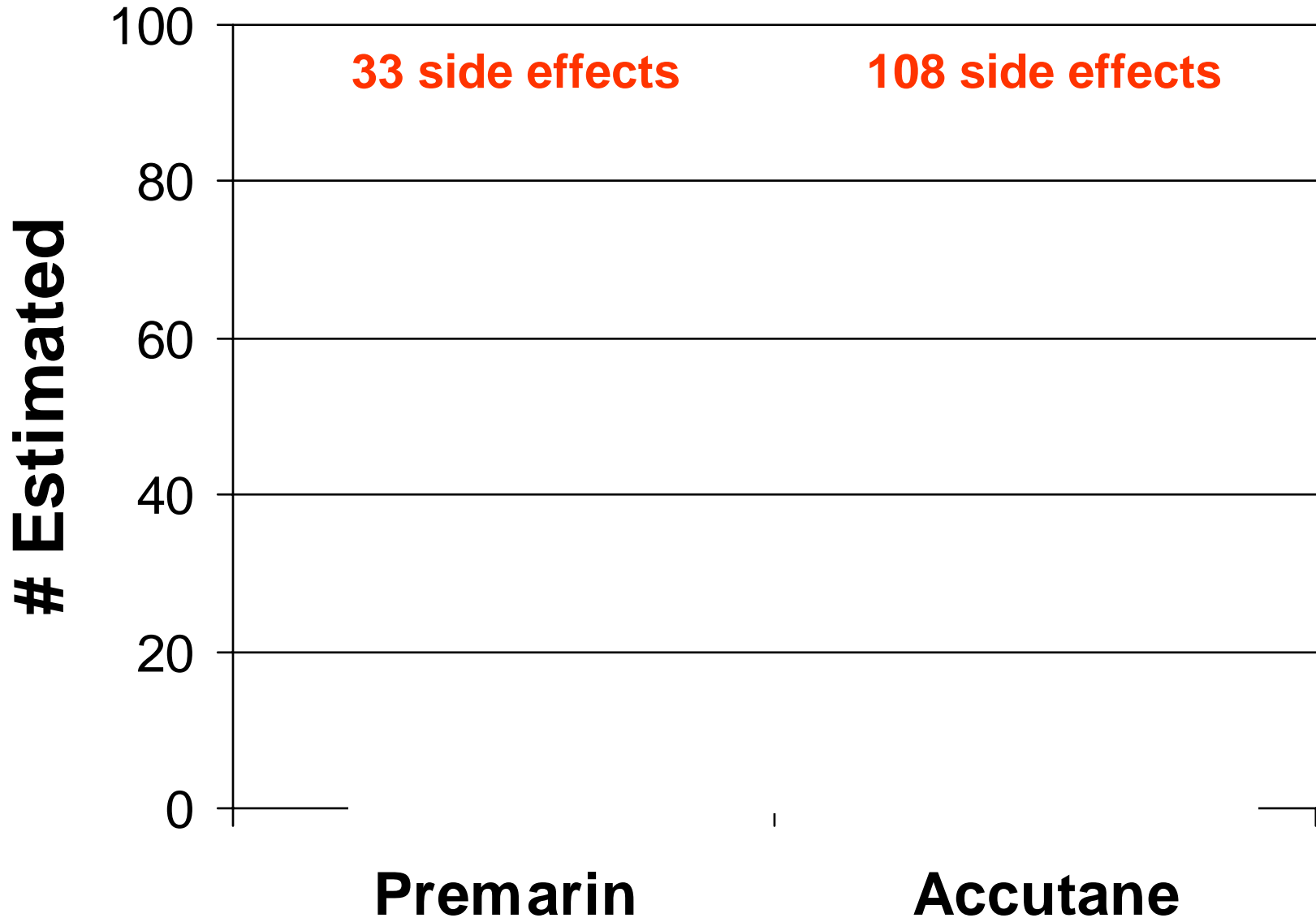
Side Effects

SIDE EFFECTS: # Estimation

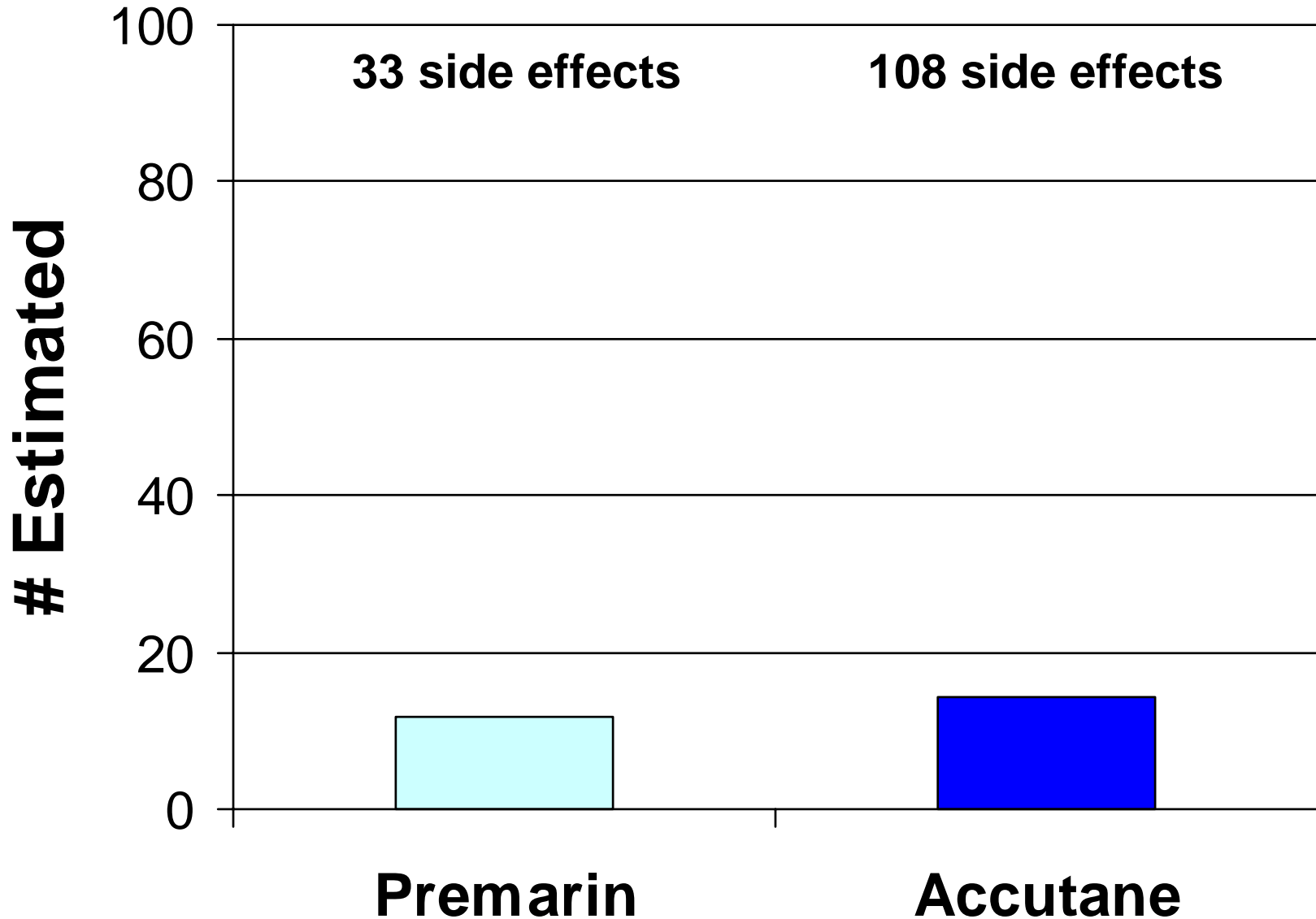
SIDE EFFECTS: # Estimation



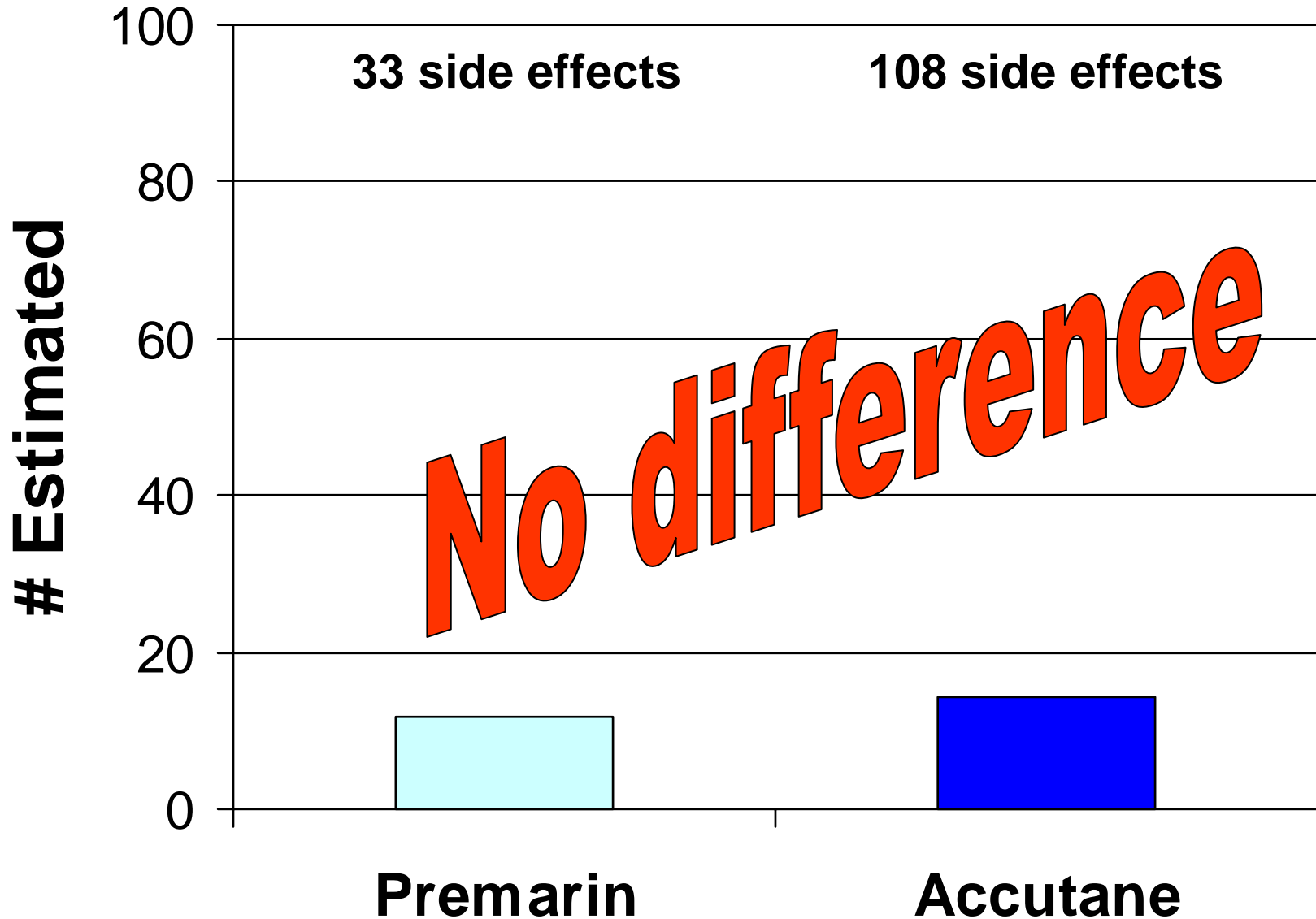
SIDE EFFECTS: # Estimation



SIDE EFFECTS: # Estimation

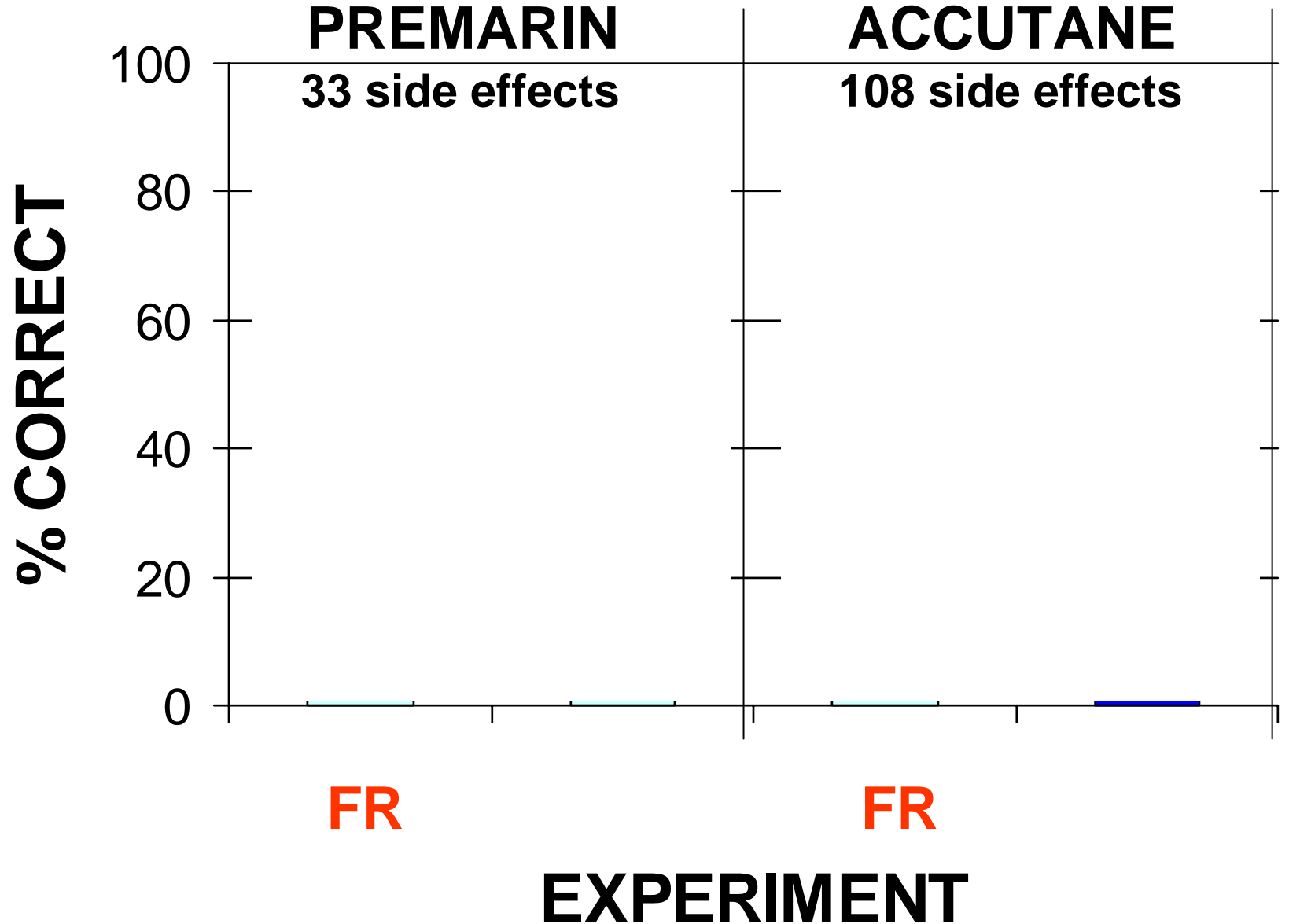


SIDE EFFECTS: # Estimation

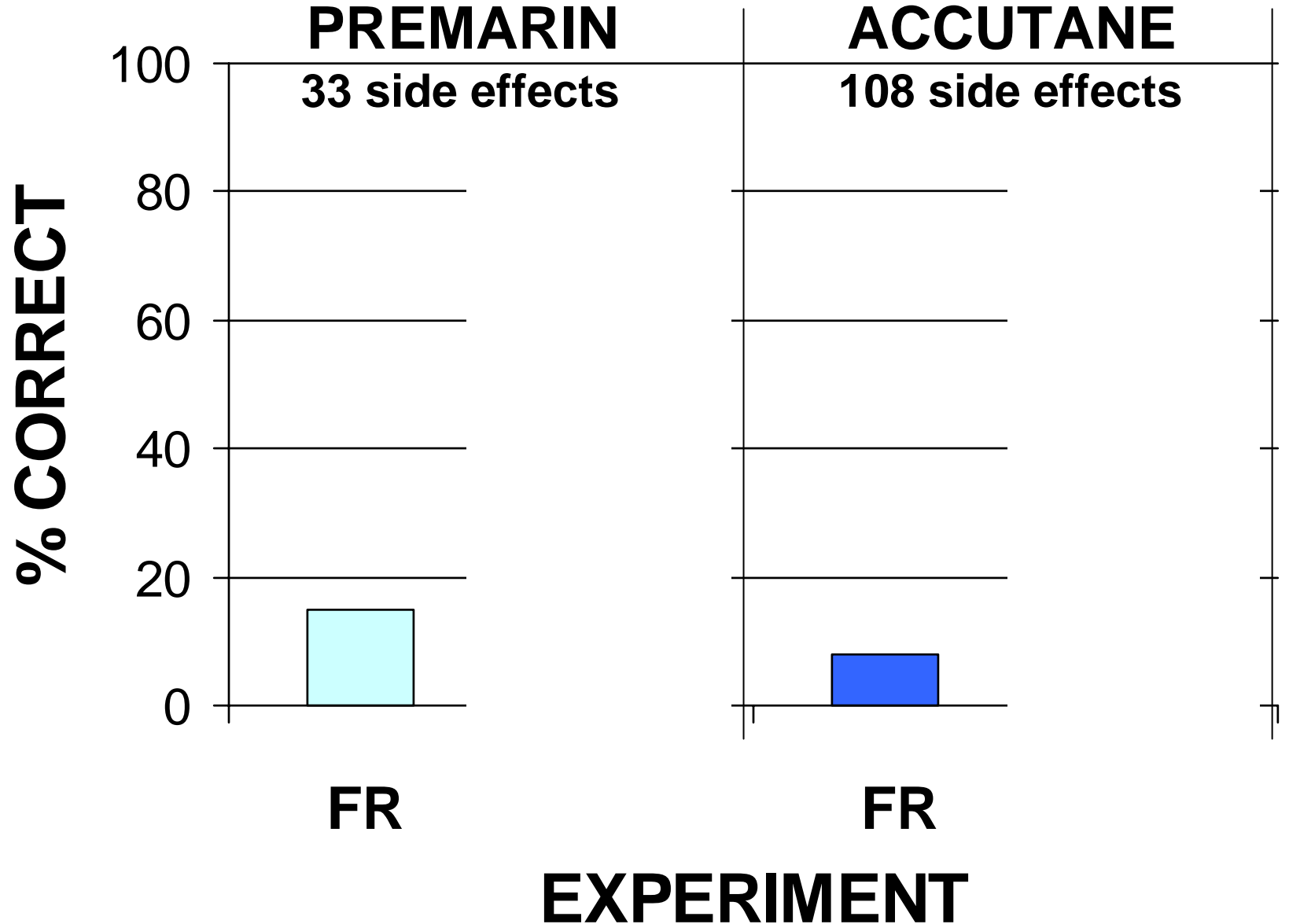


SIDE EFFECTS: Other Tasks

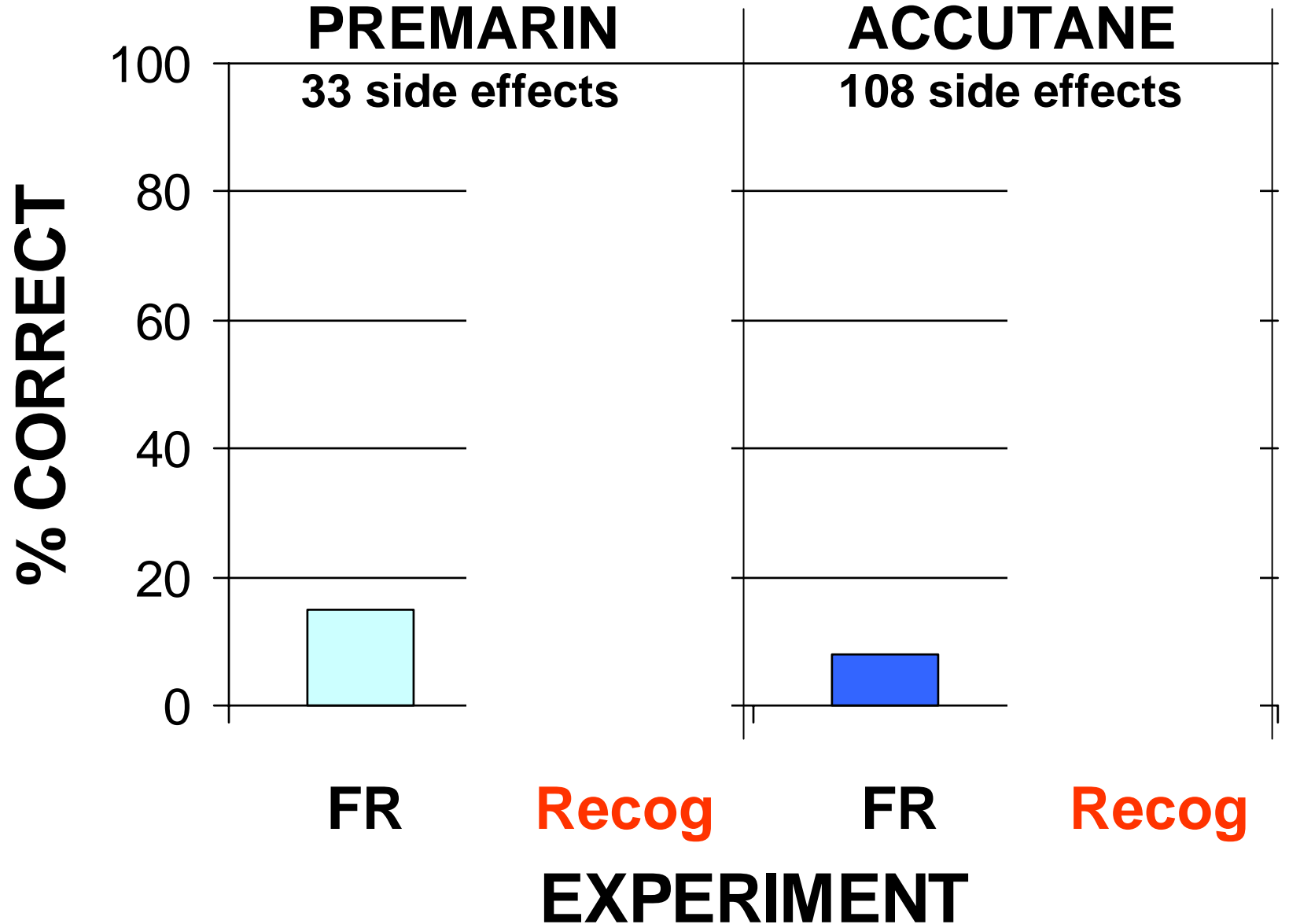
Side Effects



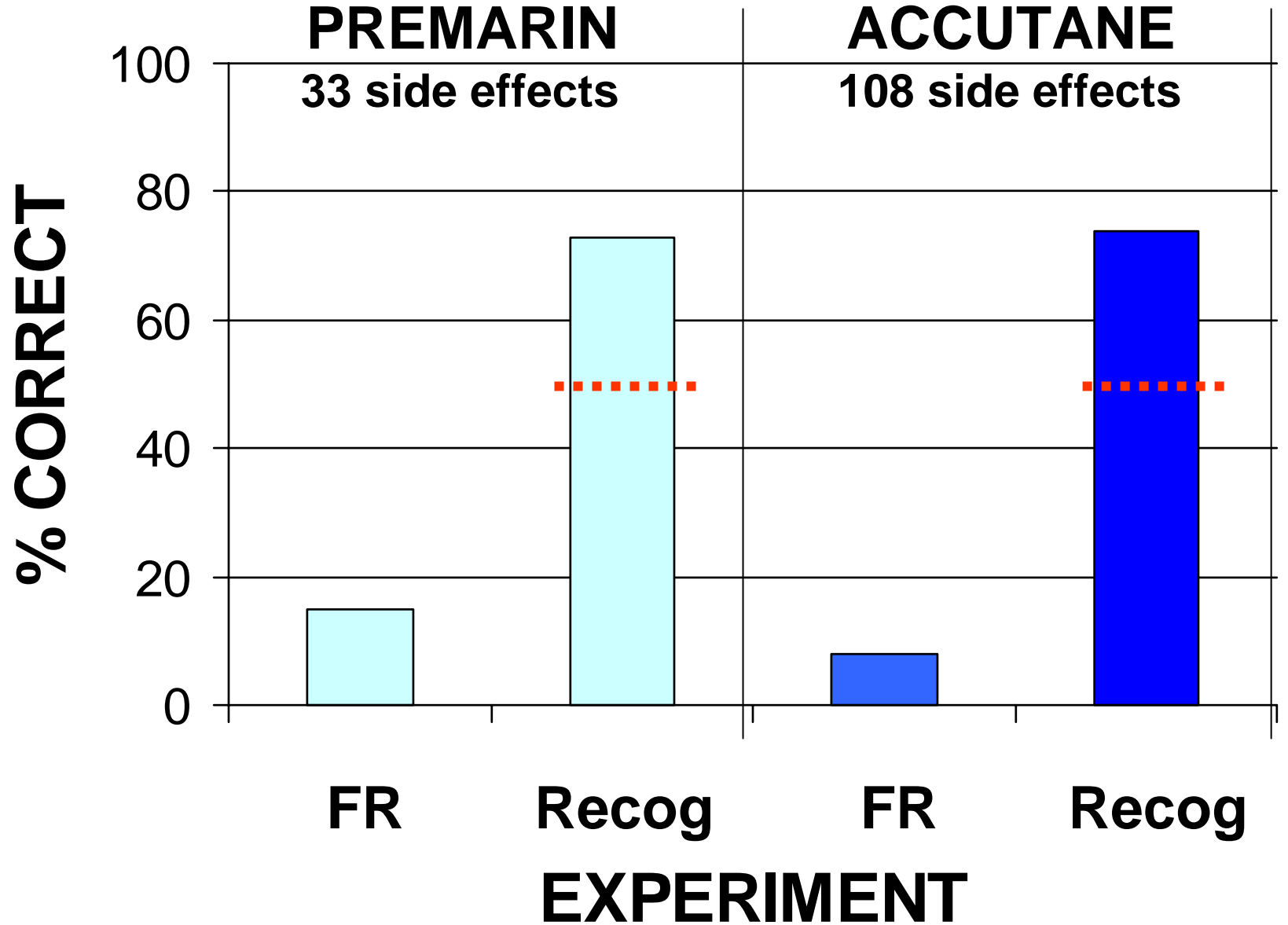
Side Effects



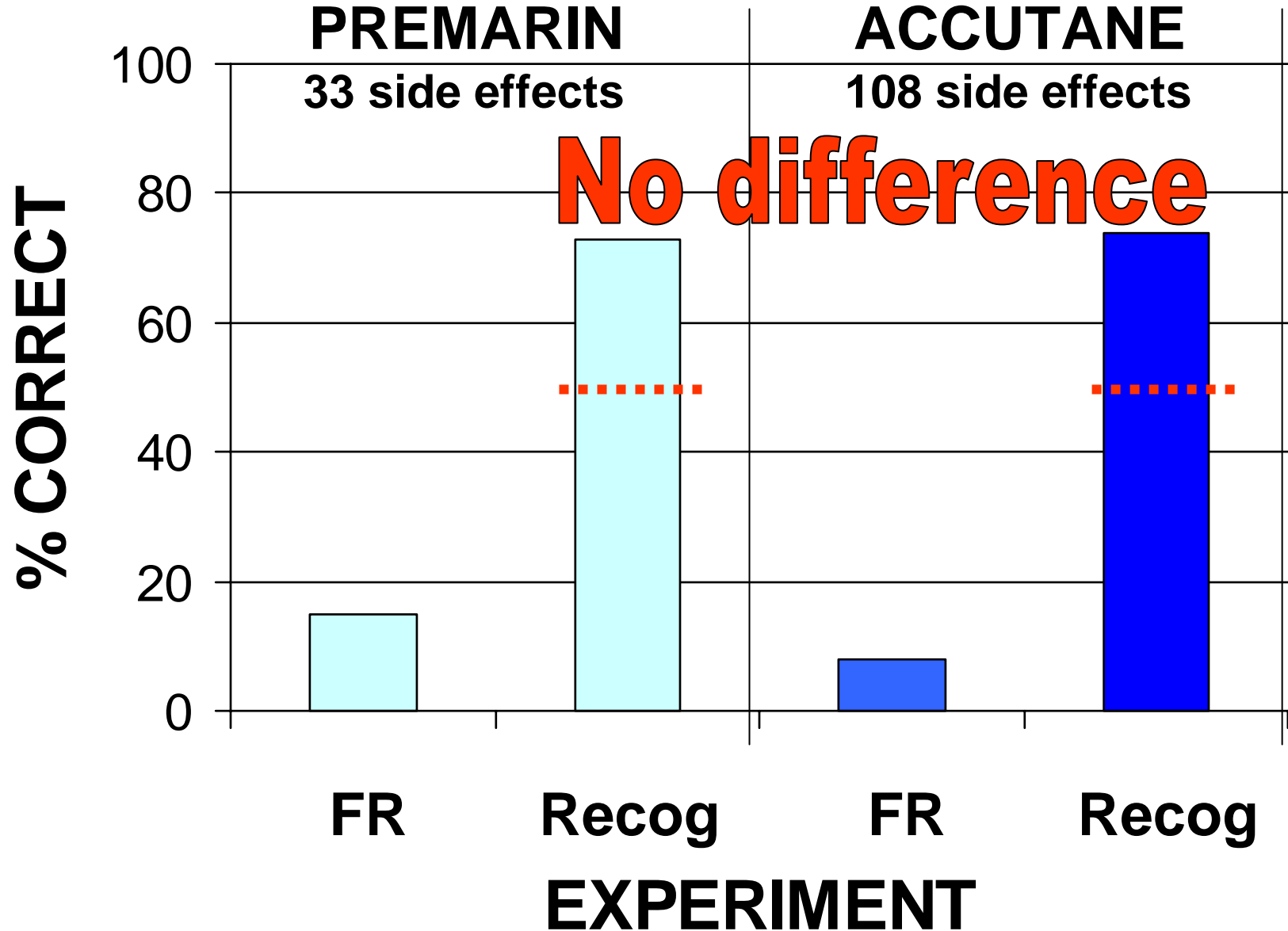
Side Effects



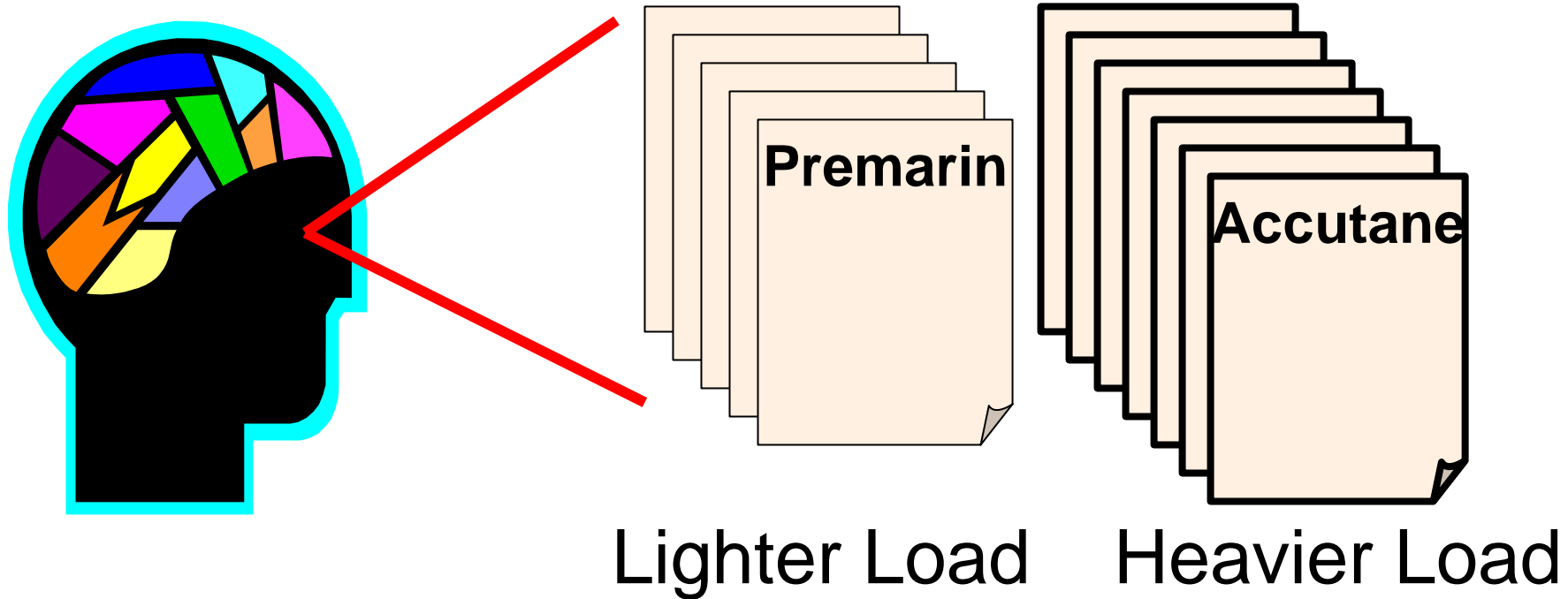
Side Effects



Side Effects



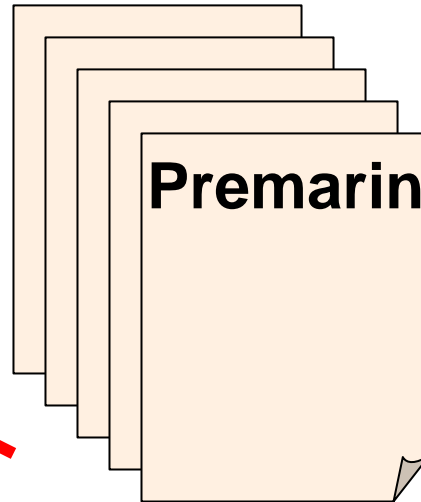
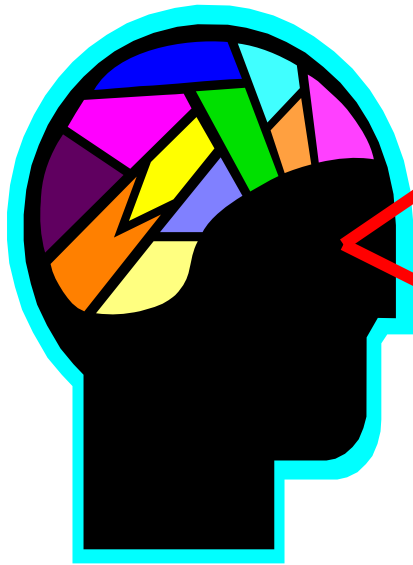
Information Load



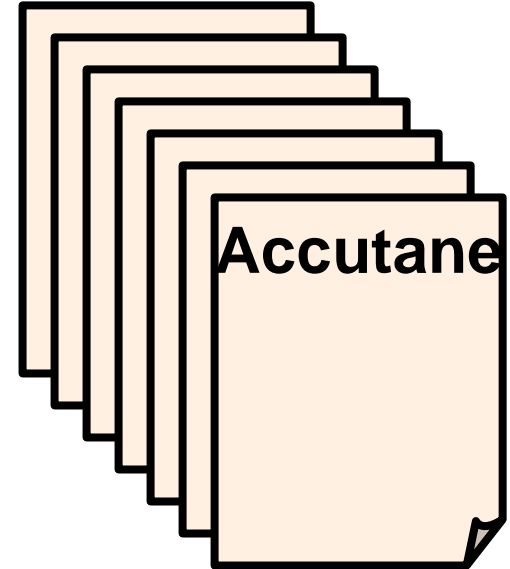
Prediction

Performance on Premarin > Accutane

Information Load



Lighter Load



Heavier Load

~~Prediction~~

Performance on Premarin = Accutane

FOCUS

Accutane

Medication Guide



Key Educational Message

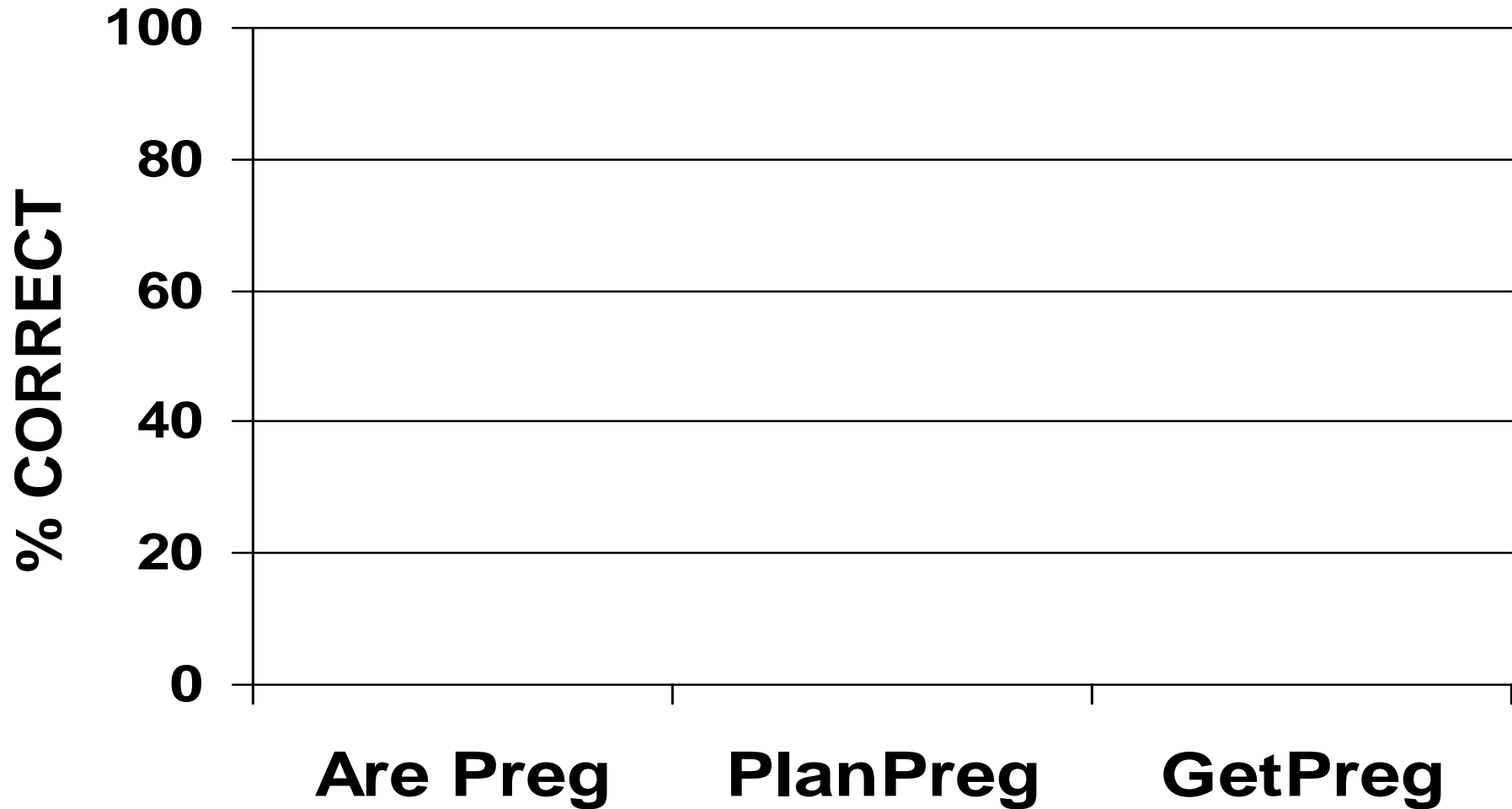


Key Educational
Message

*“What is the most important information
I should know about Accutane?”*

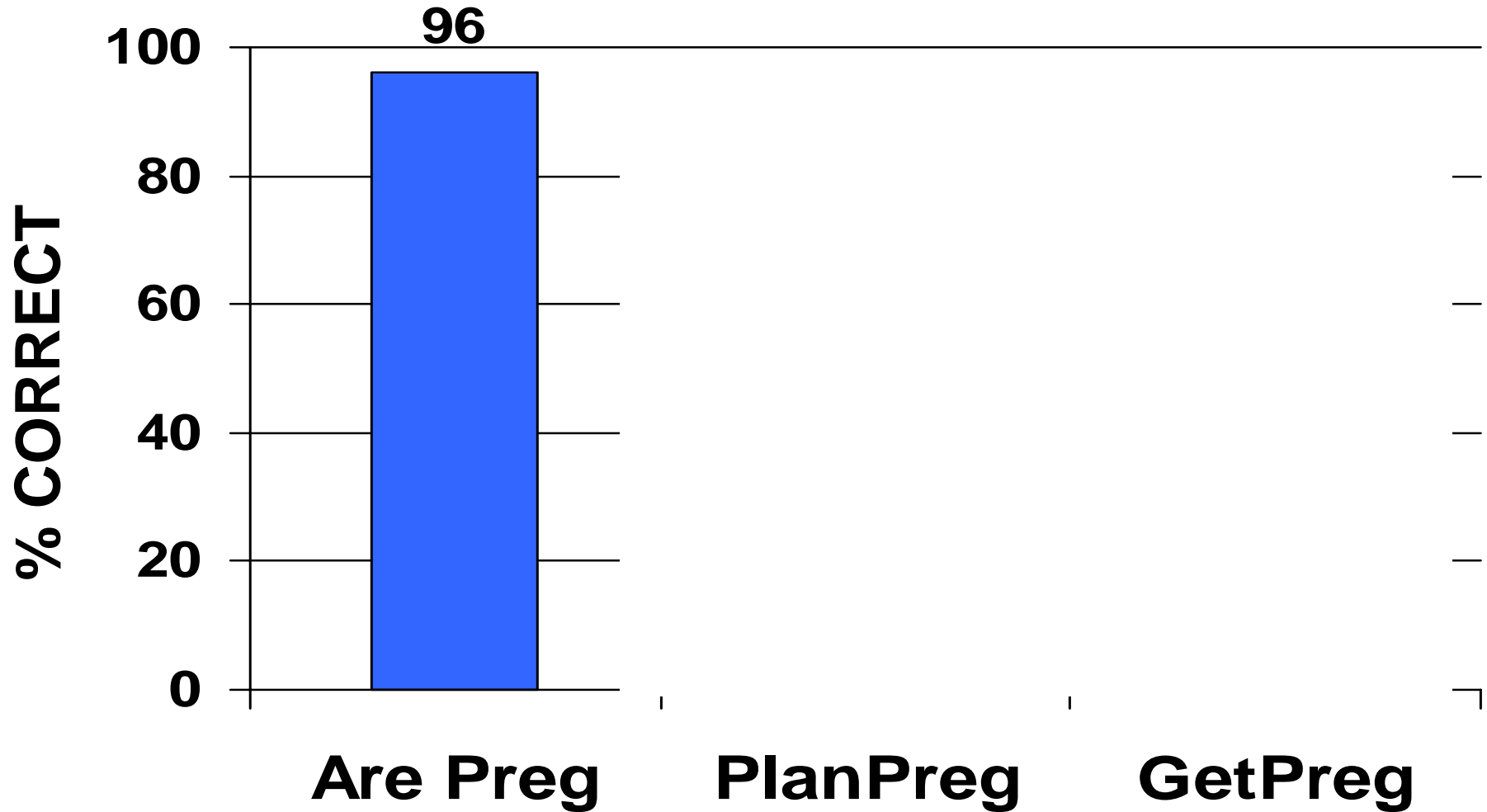
Accutane

Pregnancy



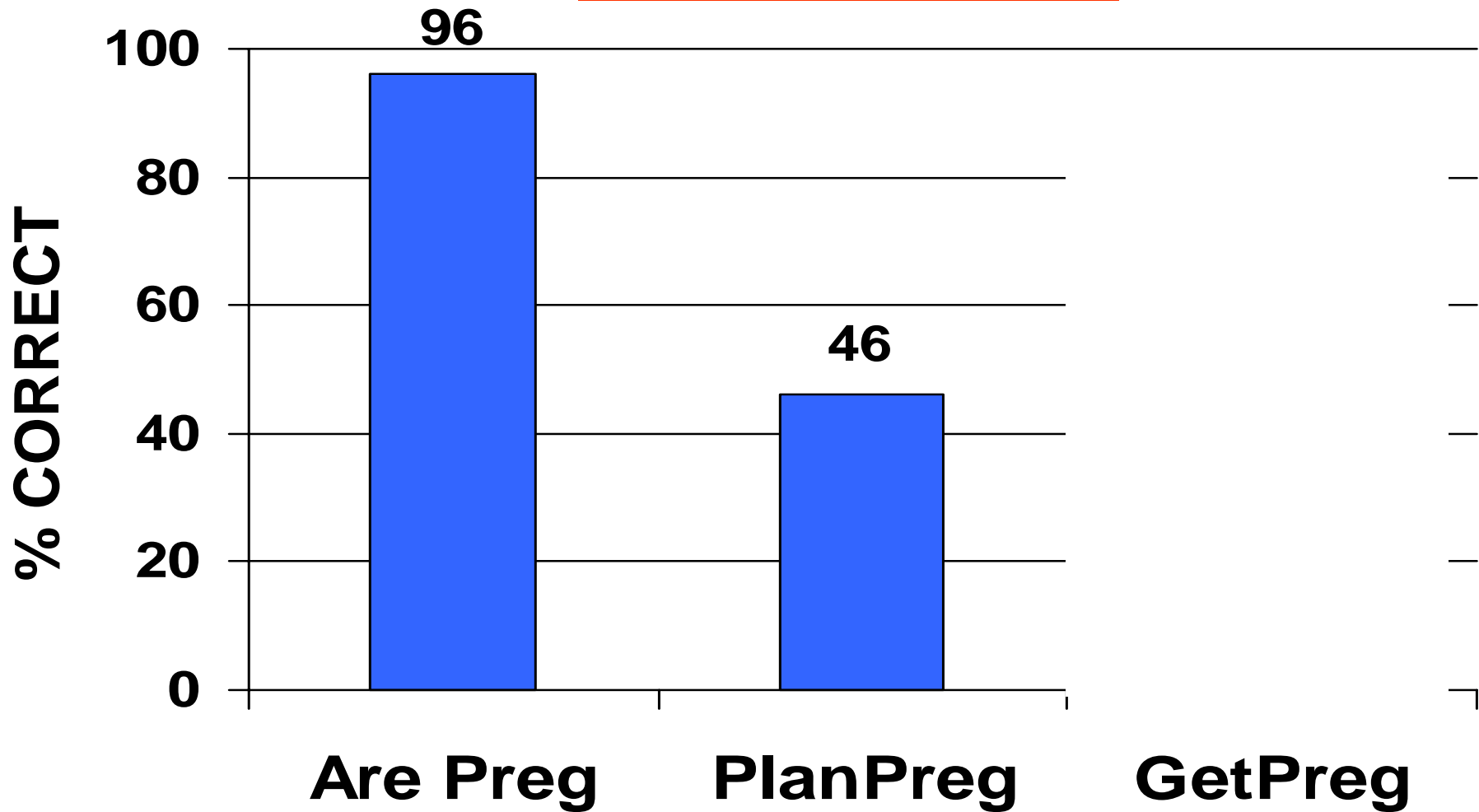
Accutane

Pregnancy



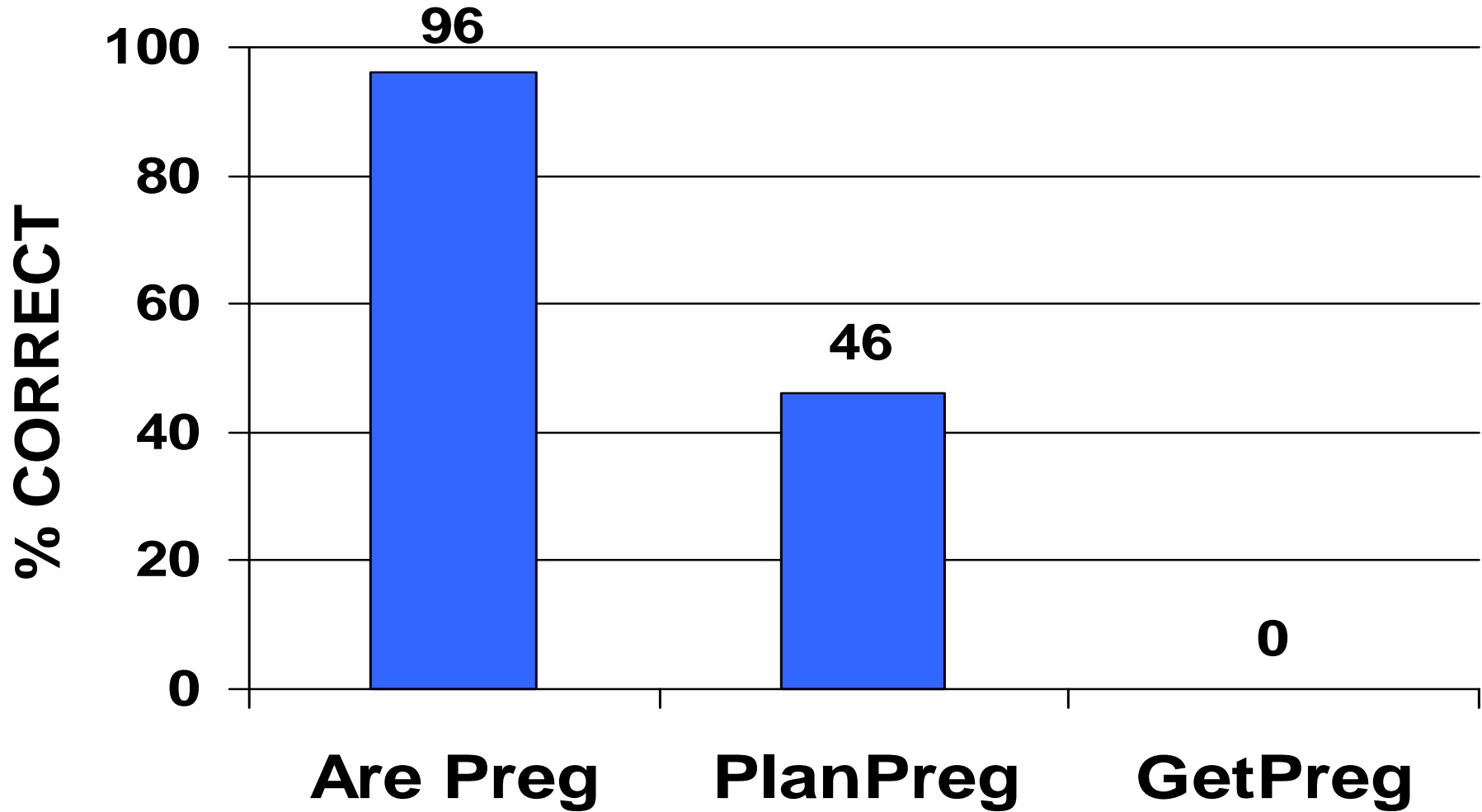
Accutane

Pregnancy



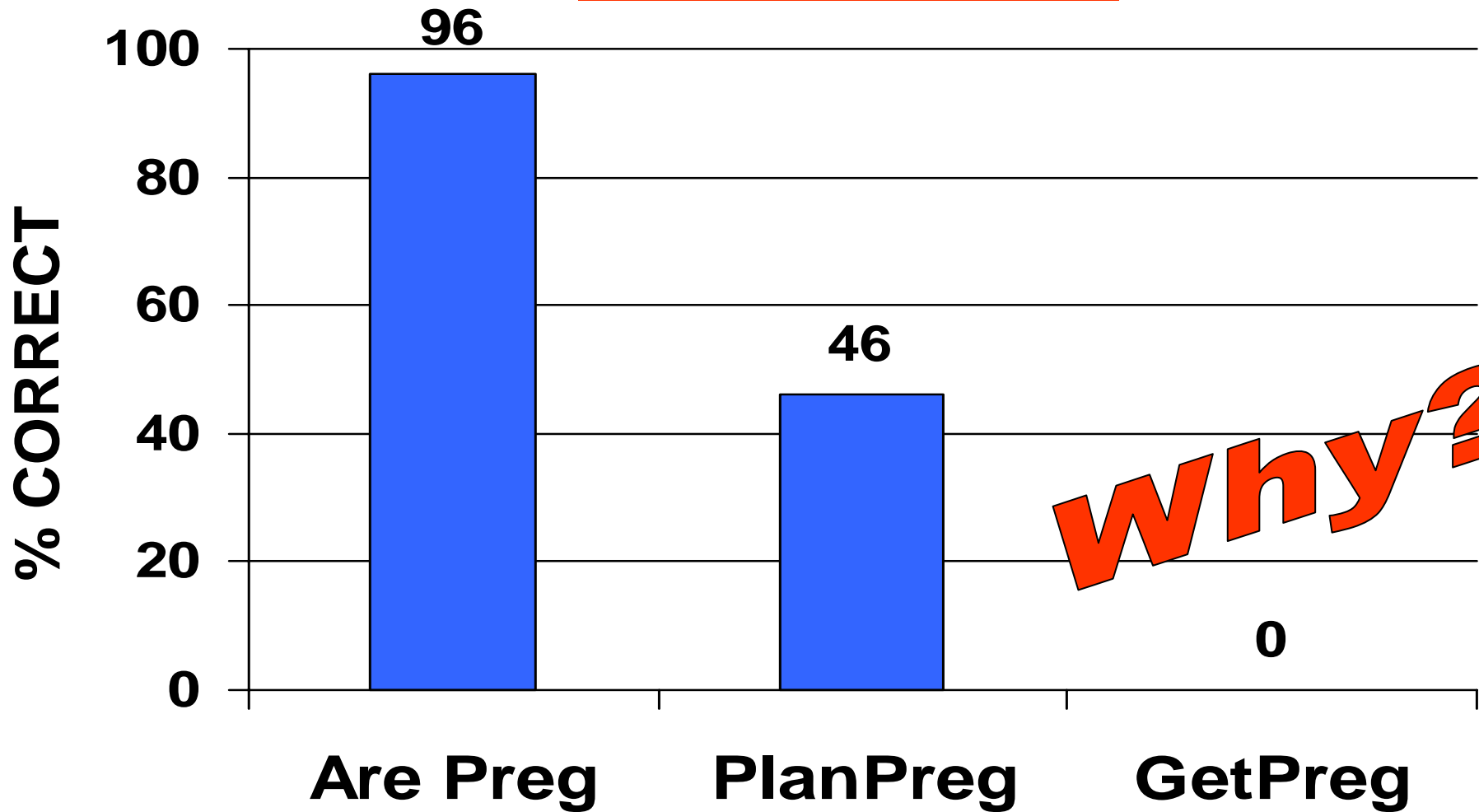
Accutane

Pregnancy



Accutane

Pregnancy



why?

- Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
- Have a change in your appetite or body weight
- Have trouble concentrating
- Withdraw from your friends or family
- Feel like you have no energy
- Have feelings of worthlessness or inappropriate guilt
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts)

What is Accutane?

Accutane is used to treat the most severe form of acne (nodular acne) that cannot be cleared up by any other acne treatments, including antibiotics. In severe nodular acne, many red, swollen, tender lumps form in the skin. These can be the size of pencil erasers or larger. If untreated, nodular acne can lead to permanent scars. However, because Accutane can have serious side effects, you should talk with your prescriber about all of the possible treatments for your acne, and whether Accutane's possible benefits outweigh its possible risks.

Who should not take Accutane?

- **Do not take Accutane if you are pregnant, plan to become pregnant, or become pregnant during Accutane treatment.** Accutane causes severe birth defects. All females should read the section "What are the important warnings for females taking Accutane?" for more information and warnings about Accutane and pregnancy.
- Do not take Accutane unless you completely understand its possible risks and are willing to follow all of the instructions in this Medication Guide.

Tell your prescriber if you or someone in your family has had any kind of mental problems, asthma, liver disease, diabetes, heart disease, osteoporosis (bone loss), weak bones, anorexia nervosa (an eating disorder where people eat too little), or any other important health problems. Tell your prescriber about any food or drug allergies you have had in the past. These problems do not necessarily mean you cannot take Accutane, but your prescriber needs this information to discuss if Accutane is right for you.

How should I take Accutane?

- You will get no more than a 30-day supply of Accutane at a time, to be sure you check in with your prescriber each month to discuss side effects.
- Your prescription should have a special yellow self-adhesive sticker attached to it. The sticker is **YELLOW**. If your prescription does not have this yellow self-adhesive sticker, call your prescriber. The pharmacy should not fill your prescription unless it has the yellow self-adhesive sticker.

Who should not take Accutane?



Original

Who should not take Accutane?

- **Do not take Accutane if you are pregnant, plan to become pregnant, or become pregnant during Accutane treatment.** Accutane causes severe birth defects. ~~All females should read the section "What are the important warnings for females taking Accutane?" for more information and warnings about Accutane and pregnancy.~~
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Enhanced

BEFORE TAKING ACCUTANE

Do NOT start taking Accutane:

--Do NOT take Accutane if you are pregnant, plan to become pregnant, or become pregnant during Accutane treatment. Accutane causes severe birth defects. All females should read the section "Warnings for Females" for more information about Accutane and pregnancy.

--Do NOT take Accutane unless you completely understand its possible risks and are willing to follow all of the instructions in this Medication Guide.

Tell your prescriber about:

Health Problems

Tell your prescriber if you or someone in your family has had any of these health problems

- mental problems
- asthma
- liver disease
- diabetes
- heart disease
- osteoporosis (bone loss)
- weak bones
- anorexia nervosa (eating disorder where people eat too little)
- any other important health problems

Allergies

Tell your prescriber about any food or drug allergies you have had in the past. These problems do not necessarily mean you cannot take Accutane, but your prescriber needs this information to discuss if Accutane is right for you.

**New titles
(Time Zones)**

WHILE TAKING ACCUTANE

Getting your prescription

You will get no more than a 30-day supply of Accutane at a time, to be sure you check in with your prescriber each month to discuss side effects (and get a pregnancy test, if you are female).

Your prescription should have a special self-adhesive sticker attached to it. The sticker is yellow. If your prescription does not have this yellow sticker, call your prescriber. The pharmacy should not fill your prescription unless it has the yellow self-adhesive sticker.

How should I take Accutane?

--The amount of Accutane you take has been specially chosen for you and may change during treatment.

--You will take Accutane 2 times a day with a meal, unless your prescriber tells you otherwise. Swallow your Accutane capsules with a full glass of liquid. This will help prevent the medication inside the capsule from irritating the lining of your esophagus (connection between mouth and stomach). For the same reason, do not chew or suck on the capsule.

BEFORE TAKING ACCUTANE

Do NOT start taking Accutane:

--Do NOT take Accutane if you are pregnant, plan to become pregnant, **or become pregnant during Accutane treatment.** Accutane causes severe birth defects. All females should read the section "Warnings for Females" for more information about Accutane and pregnancy.

--Do NOT take Accutane unless you completely understand its possible risks and are willing to follow all of the instructions in this Medication Guide.

Tell your prescriber about:

Health Problems

Tell your prescriber if you or someone in your family has had any of these health problems

- mental problems
- asthma
- liver disease
- diabetes
- heart disease
- osteoporosis (bone loss)
- weak bones
- anorexia nervosa (eating disorder where people eat too little)
- any other important health problems

Allergies

Tell your prescriber about any food or drug allergies you have had in the past. These problems do not necessarily mean you cannot take Accutane, but your prescriber needs this information to discuss if Accutane is right for you.

WHILE TAKING ACCUTANE

Getting your prescription

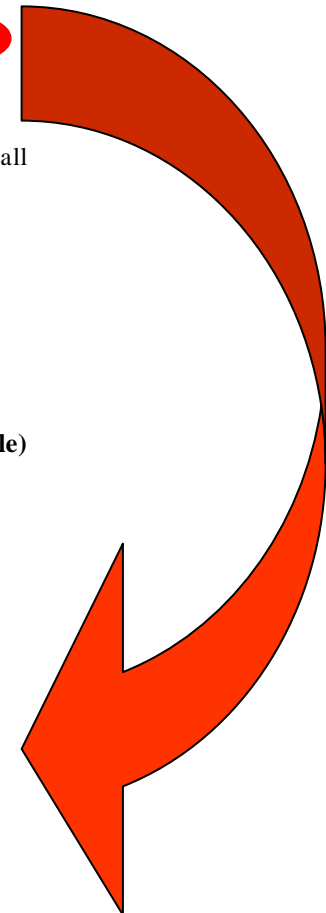
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Alternative Representations

PREMARIN

Patient
Package
Insert

AC CUTANE

Medication
Guide

Alternative Representations

AC CUTANE

Medication
Guide

Original Representation

Sample Pages

AC CUTANE

Medication
Guide

MEDICATION GUIDE FOR ALL PATIENTS

ACCUTANE[®] Capsules (isotretinoin)

Read this Medication Guide every time you get a prescription or a refill for Accutane (ACK-u-tane). There may be new information. This information does not take the place of talking with your prescriber (doctor or other health care provider).

What is the most important information I should know about Accutane?

Accutane is used to treat a type of severe acne (nodular acne) that has not been helped by other treatments, including antibiotics. However, Accutane can cause serious side effects. Before starting Accutane, discuss with your prescriber how bad your acne is, the possible benefits of Accutane, and its possible side effects, to decide if Accutane is right for you. Your prescriber will ask you to read and sign a form or forms indicating you understand some of the serious risks of Accutane.

Possible serious side effects of taking Accutane include *birth defects* and *mental disorders*.

1. **Birth defects. Accutane can cause birth defects (deformed babies) if taken by a pregnant woman.** It can also cause miscarriage (losing the baby before birth), premature (early) birth, or death of the baby. Do not take Accutane if you are pregnant or plan to become pregnant while you are taking Accutane. Do not get pregnant for 1 month after you stop taking Accutane. Also, if you get pregnant while taking Accutane, stop taking it right away and call your prescriber.

All females should read the section in this Medication Guide "What are the important warnings for females taking Accutane?"

2. **Mental problems and suicide.** Some patients, while taking Accutane or soon after stopping Accutane, have become depressed or developed other serious mental problems. Symptoms of these problems include sad, "anxious" or empty mood, irritability, anger, loss of pleasure or interest in social or sports activities, sleeping too much or too little, changes in weight or appetite, school or work performance going down, or trouble concentrating. Some patients taking Accutane have had thoughts about hurting themselves or putting an end to their own lives (suicidal thoughts). Some people tried to end their own lives. And some people have ended their own lives. There were reports that some of these people did not appear depressed. There have been reports of patients on Accutane becoming aggressive or violent. No one knows if Accutane caused these behaviors or if they would have happened even if the person did not take Accutane.

All patients should read the section in this Medication Guide "What are the signs of mental problems?"

For other possible serious side effects of Accutane, see "What are the possible side effects of Accutane?" in this Medication Guide.

What are the important warnings for females taking Accutane?

You must not become pregnant while taking Accutane, or for 1 month after you stop taking Accutane. Accutane can cause severe birth defects in babies of women who take it while they are pregnant, even if they take Accutane for only a short time. **There is an extremely high risk that**

your baby will be deformed or will die if you are pregnant while taking Accutane. Taking Accutane also increases the chance of miscarriage and premature births.

Female patients will not get their first prescription for Accutane unless there is proof they have had 2 negative pregnancy tests. The first test must be done when your prescriber decides to prescribe Accutane. The second pregnancy test must be done during the first 5 days of the menstrual period right before starting Accutane therapy, or as instructed by your prescriber. Each month of treatment, you must have a negative result from a urine or serum pregnancy test. Female patients cannot get another prescription for Accutane unless there is proof that they have had a negative pregnancy test.

A yellow self-adhesive Accutane Qualification Sticker on your prescription indicates to the pharmacist that you are qualified by your prescriber to get Accutane.

While you are taking Accutane, you **must** use effective birth control. **You must use 2 separate effective forms of birth control at the same time** for at least 1 month before starting Accutane, while you take it, and for 1 month after you stop taking it. You can either discuss effective birth control methods with your prescriber or go for a free visit to discuss birth control with another physician or family planning expert. Your prescriber can arrange this free visit, which will be paid for by the manufacturer.

You must use 2 separate forms of effective birth control because any method, including birth control pills and sterilization, can fail. There are only 2 reasons you would not need to use 2 separate methods of effective birth control:

1. You have had your womb removed by surgery (a hysterectomy).
2. You are absolutely certain you will not have genital-to-genital sexual contact with a male before, during, and for 1 month after Accutane treatment.

If you have sex at any time without using 2 forms of effective birth control, get pregnant, or miss your period, stop using Accutane and call your prescriber right away.

All patients should read the rest of this Medication Guide.

What are the signs of mental problems?

Tell your prescriber if, to the best of your knowledge, you or someone in your family has ever had any mental illness, including depression, suicidal behavior, or psychosis. Psychosis means a loss of contact with reality, such as hearing voices or seeing things that are not there. Also, tell your prescriber if you take medicines for any of these problems.

Stop using Accutane and tell your provider right away if you:

- Start to feel sad or have crying spells
- Lose interest in activities you once enjoyed
- Sleep too much or have trouble sleeping

- Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
- Have a change in your appetite or body weight
- Have trouble concentrating
- Withdraw from your friends or family
- Feel like you have no energy
- Have feelings of worthlessness or inappropriate guilt
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts)

What is Accutane?

Accutane is used to treat the most severe form of acne (nodular acne) that cannot be cleared up by any other acne treatments, including antibiotics. In severe nodular acne, many red, swollen, tender lumps form in the skin. These can be the size of pencil erasers or larger. If untreated, nodular acne can lead to permanent scars. However, because Accutane can have serious side effects, you should talk with your prescriber about all of the possible treatments for your acne, and whether Accutane's possible benefits outweigh its possible risks.

Who should not take Accutane?

- **Do not take Accutane if you are pregnant, plan to become pregnant, or become pregnant during Accutane treatment.** Accutane causes severe birth defects. All females should read the section "What are the important warnings for females taking Accutane?" for more information and warnings about Accutane and pregnancy.
- Do not take Accutane unless you completely understand its possible risks and are willing to follow all of the instructions in this Medication Guide.

Tell your prescriber if you or someone in your family has had any kind of mental problems, asthma, liver disease, diabetes, heart disease, osteoporosis (bone loss), weak bones, anorexia nervosa (an eating disorder where people eat too little), or any other important health problems. Tell your prescriber about any food or drug allergies you have had in the past. These problems do not necessarily mean you cannot take Accutane, but your prescriber needs this information to discuss if Accutane is right for you.

How should I take Accutane?

- You will get no more than a 30-day supply of Accutane at a time, to be sure you check in with your prescriber each month to discuss side effects.
- Your prescription should have a special yellow self-adhesive sticker attached to it. The sticker is YELLOW. If your prescription does not have this yellow self-adhesive sticker, call your prescriber. The pharmacy should not fill your prescription unless it has the yellow self-adhesive sticker.

MEDICATION GUIDE FOR ALL PATIENTS

ACCUTANE® Capsules (isotretinoin)

Read this Medication Guide every time you get a prescription or a refill for Accutane (ACK-u-tane). There may be new information. This information does not take the place of talking with your prescriber (doctor or other health care provider).

What is the most important information I should know about Accutane?

Accutane is used to treat a type of severe acne (nodular acne) that has not been helped by other treatments, including antibiotics. However, Accutane can cause serious side effects. Before starting Accutane, discuss with your prescriber how bad your acne is, the possible benefits of Accutane, and its possible side effects, to decide if Accutane is right for you. Your prescriber will ask you to read and sign a form or forms indicating you understand some of the serious risks of Accutane.

Possible serious side effects of taking Accutane include birth defects and mental disorders.

1. **Birth defects.** Accutane can cause birth defects (deformed babies) if taken by a pregnant woman. It can also cause miscarriage (losing the baby before birth), premature (early) birth, or death of the baby. Do not take Accutane if you are pregnant or plan to become pregnant while you are taking Accutane. Do not get pregnant for 1 month after you stop taking Accutane. Also, if you get pregnant while taking Accutane, stop taking it right away and call your prescriber.

All females should read the section in this Medication Guide "What are the important warnings for females taking Accutane?"

2. **Mental problems and suicide.** Some patients, while taking Accutane or soon after stopping Accutane, have become depressed or developed other serious mental problems. Symptoms of these problems include sad, "anxious" or empty mood, irritability, anger, loss of pleasure or interest in social or sports activities, sleeping too much or too little, changes in weight or appetite, school or work performance going down, or trouble concentrating. Some patients taking Accutane have had thoughts about hurting themselves or putting an end to their own lives (suicidal thoughts). Some people tried to end their own lives. And some people have ended their own lives. There were reports that some of these people did not appear depressed. There have been reports of patients on Accutane becoming aggressive or violent. No one knows if Accutane caused these behaviors or if they would have happened even if the person did not take Accutane.

All patients should read the section in this Medication Guide "What are the signs of mental problems?"

For other possible serious side effects of Accutane, see "What are the possible side effects of Accutane?" in this Medication Guide.

What are the important warnings for females taking Accutane?

You must not become pregnant while taking Accutane, or for 1 month after you stop taking Accutane. Accutane can cause severe birth defects in babies of women who take it while they are pregnant, even if they take Accutane for only a short time. **There is an extremely high risk that**

- The amount of Accutane you take has been specially chosen for you and may change during treatment.
- You will take Accutane 2 times a day with a meal, unless your prescriber tells you otherwise. Swallow your Accutane capsules with a full glass of liquid. This will help prevent the medication inside the capsule from irritating the lining of your esophagus (connection between mouth and stomach). For the same reason, do not chew or suck on the capsule.
- If you miss a dose, just skip that dose. Do not take 2 doses the next time.
- You should return to your prescriber as directed to make sure you don't have signs of serious side effects. Because some of Accutane's serious side effects show up in blood tests, some of these visits may involve blood tests (monthly visits for female patients should always include a urine or serum pregnancy test).

What should I avoid while taking Accutane?

- **Do not get pregnant** while taking Accutane. See "What is the most important information I should know about Accutane?" and "What are the important warnings for females taking Accutane?"
- **Do not breast feed** while taking Accutane and for 1 month after stopping Accutane. We do not know if Accutane can pass through your milk and harm the baby.
- **Do not give blood** while you take Accutane and for 1 month after stopping Accutane. If someone who is pregnant gets your donated blood, her baby may be exposed to Accutane and may be born with birth defects.
- **Do not take vitamin A supplements.** Vitamin A in high doses has many of the same side effects as Accutane. Taking both together may increase your chance of getting side effects.
- **Do not have cosmetic procedures to smooth your skin, including waxing, dermabrasion, or laser procedures, while you are using Accutane and for at least 6 months after you stop.** Accutane can increase your chance of scarring from these procedures. Check with your prescriber for advice about when you can have cosmetic procedures.
- **Avoid sunlight and ultraviolet lights** as much as possible. Tanning machines use ultraviolet lights. Accutane may make your skin more sensitive to light.
- **Do not use birth control pills that do not contain estrogen ("minipills").** They may not work while you take Accutane. Ask your prescriber or pharmacist if you are not sure what type you are using.
- **Talk with your doctor if you plan to take other drugs or herbal products.** This is especially important for patients using birth control pills and other hormonal types of birth control because the birth control may not work as effectively if you are taking certain drugs.

your baby will be deformed or will die if you are pregnant while taking Accutane. Taking Accutane also increases the chance of miscarriage and premature births.

Female patients will not get their first prescription for Accutane unless there is proof they have had 2 negative pregnancy tests. The first test must be done when your prescriber decides to prescribe Accutane. The second pregnancy test must be done during the first 5 days of the menstrual period right before starting Accutane therapy, or as instructed by your prescriber. Each month of treatment, you must have a negative result from a urine or serum pregnancy test. Female patients cannot get another prescription for Accutane unless there is proof that they have had a negative pregnancy test.

A yellow self-adhesive Accutane Qualification Sticker on your prescription indicates to the pharmacist that you are qualified by your prescriber to get Accutane.

While you are taking Accutane, you **must use effective birth control. You must use 2 separate effective forms of birth control at the same time** for at least 1 month before starting Accutane, while you take it, and for 1 month after you stop taking it. You can either discuss effective birth control methods with your prescriber or go for a free visit to discuss birth control with another physician or family planning expert. Your prescriber can arrange this [free visit](#), which will be paid for by the manufacturer.

You must use 2 separate forms of effective birth control because any method, including birth control pills and sterilization, can fail. There are only 2 reasons you would not need to use 2 separate methods of effective birth control:

1. You have had your womb removed by surgery (a hysterectomy).
2. You are absolutely certain you will not have genital-to-genital sexual contact with a male before, during, and for 1 month after Accutane treatment.

If you have sex at any time without using 2 forms of effective birth control, get pregnant, or miss your period, stop using Accutane and call your prescriber right away.

All patients should read the rest of this Medication Guide.

What are the signs of mental problems?

Tell your prescriber if, to the best of your knowledge, you or someone in your family has ever had any mental illness, including depression, suicidal behavior, or psychosis. Psychosis means a loss of contact with reality, such as hearing voices or seeing things that are not there. Also, tell your prescriber if you take medicines for any of these problems.

Stop using Accutane and tell your provider right away if you:

- Start to feel sad or have crying spells
- Lose interest in activities you once enjoyed
- Sleep too much or have trouble sleeping

- or herbal products. You should not take the herbal supplement St. John's Wort because this herbal supplement may make birth control pills not work as effectively.

- **Talk with your doctor if you are currently taking an oral or injected corticosteroid or anticonvulsant (seizure) medication prior to using Accutane.** These drugs may weaken your bones.
- **Do not share Accutane with other people.** It can cause birth defects and other serious health problems.
- **Do not take Accutane with antibiotics unless you talk to your prescriber.** For some antibiotics, you may have to stop taking Accutane until the antibiotic treatment is finished. Use of both drugs together can increase the chances of getting increased pressure in the brain.

What are the possible side effects of Accutane?

Accutane has possible serious side effects

- **Accutane can cause birth defects, premature births, and death in babies** whose mothers took Accutane while they were pregnant. See "What is the most important information I should know about Accutane?" and "What are the important warnings for females taking Accutane?"
- **Serious mental health problems.** See "What is the most important information I should know about Accutane?"
- **Serious brain problems.** Accutane can increase the pressure in your brain. This can lead to permanent loss of sight, or in rare cases, death. Stop taking Accutane and call your prescriber right away if you get any of these signs of increased brain pressure: bad headache, blurred vision, dizziness, nausea, or vomiting. Also, some patients taking Accutane have had seizures (convulsions) or stroke.
- **Abdomen (stomach area) problems.** Certain symptoms may mean that your internal organs are being damaged. These organs include the liver, pancreas, bowel (intestines), and esophagus (connection between mouth and stomach). If your organs are damaged, they may not get better even after you stop taking Accutane. Stop taking Accutane and call your prescriber if you get severe stomach, chest or bowel pain, trouble swallowing or painful swallowing, new or worsening heartburn, diarrhea, rectal bleeding, yellowing of your skin or eyes, or dark urine.
- **Bone and muscle problems.** Accutane may affect bones, muscles, and ligaments and cause pain in your joints or muscles. Tell your prescriber if you plan vigorous physical activity during treatment with Accutane. Tell your prescriber if you develop pain, particularly back pain or joint pain. There are reports that some patients have had stunted growth after taking Accutane for acne as directed. There are also some reports of broken bones or reduced healing of broken bones after taking Accutane for acne as directed. No one knows if taking Accutane for acne will affect your bones. If you have a broken bone, tell your provider that

- Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
- Have a change in your appetite or body weight
- Have trouble concentrating
- Withdraw from your friends or family
- Feel like you have no energy
- Have feelings of worthlessness or inappropriate guilt
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts)

What is Accutane?

Accutane is used to treat the most severe form of acne (nodular acne) that cannot be cleared up by any other acne treatments, including antibiotics. In severe nodular acne, many red, swollen, tender lumps form in the skin. These can be the size of pencil erasers or larger. If untreated, nodular acne can lead to permanent scars. However, because Accutane can have serious side effects, you should talk with your prescriber about all of the possible treatments for your acne, and whether Accutane's possible benefits outweigh its possible risks.

Who should not take Accutane?

- **Do not take Accutane if you are pregnant, plan to become pregnant, or become pregnant during Accutane treatment.** Accutane causes severe birth defects. All females should read the section "What are the important warnings for females taking Accutane?" for more information and warnings about Accutane and pregnancy.

- Do not take Accutane unless you completely understand its possible risks and are willing to follow all of the instructions in this Medication Guide.

Tell your prescriber if you or someone in your family has had any kind of mental problems, asthma, liver disease, diabetes, heart disease, osteoporosis (bone loss), weak bones, anorexia nervosa (an eating disorder where people eat too little), or any other important health problems. Tell your prescriber about any food or drug allergies you have had in the past. These problems do not necessarily mean you cannot take Accutane, but your prescriber needs this information to discuss if Accutane is right for you.

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Enhanced Representation

ACCUTANE

Medication
Guide

Enhanced Representation

- Same content as original
- Plus
 - chunking
 - coding
 - enhanced side effects
 - etc.

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MOST IMPORTANT INFORMATION

What is the most important information I should know about Accutane?

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Possible serious side effects of Accutane include birth defects and mental disorders.

1) Birth Defects

If taken by a pregnant woman, Accutane can cause:

- birth defects (deformed babies)
- premature (early) birth
- miscarriage (losing the baby before birth)
- death of the baby

Do not take Accutane if you are pregnant or plan to become pregnant while you are taking Accutane. Do not get pregnant for 1 month after you stop taking Accutane. Also, if you get pregnant while taking Accutane, stop taking it right away and call your prescriber.

All females should read the section "Warnings for Females."

2) Mental problems and suicide

Some patients have become depressed or developed other serious mental problems. This happened while taking Accutane or soon after stopping Accutane. Symptoms of mental problems include:

- sad mood
- sleep too much
- school/work performance problems
- anxious mood
- sleep too little
- trouble concentrating
- empty mood
- changes in weight
- thoughts of hurting self
- irritability
- changes in appetite
- suicidal thoughts (ending own life)
- anger
- lose interest in:
- try suicide
- aggression
- social activities
- commit suicide (*may not seem depressed*)
- violence
- sports activities

No one knows if Accutane caused these behaviors or if they would have happened even if the person did not take Accutane.

All patients should read the section "Mental Problems."

For other possible serious side effects of Accutane, see "Side Effects" in this Medication Guide.

MENTAL PROBLEMS

What are the signs of mental problems?

Tell your prescriber if, to the best of your knowledge, you or someone in your family has ever had any mental illness, including

- depression
- suicidal behavior,
- psychosis (loss of contact with reality, such as hearing voices or seeing things that are not there)

Also, tell your prescriber if you take medicines for any of these problems.

Stop using Accutane and tell your provider right away if you:

- Feel sad
- Have crying spells
- Lose interest in activities you once enjoyed
- Sleep too much
- Have trouble sleeping
- Become more
 - irritable
 - angry
 - aggressive
- Have
 - temper outbursts
 - thoughts of violence
 - change in appetite
 - change in body weight
 - trouble concentrating
- Withdraw from your friends or family
- Have feelings of
 - no energy
 - worthlessness
 - inappropriate guilt
- Have thoughts about
 - hurting yourself
 - taking your own life (suicidal thoughts)

ABOUT ACCUTANE

What is Accutane?

Accutane is used to treat the most severe form of acne (nodular acne) that cannot be cleared up by any other acne treatments, including antibiotics. In severe nodular acne, many red, swollen, tender lumps form in the skin. These can be the size of pencil erasers or larger. If untreated, nodular acne can lead to permanent scars. However, because Accutane can have serious side effects, you should talk with your prescriber about all of the possible treatments for your acne, and whether Accutane's possible benefits outweigh its possible risks.

Comparison

<u>Original</u>	<u>Enhanced</u>



Accutane®

(isotretinoin capsules)



MEDICATION GUIDE (for All Patients)

(Updated June 20, 2002)

ACCUTANE® Capsules (isotretinoin)

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Possible serious side effects of taking Accutane include *birth defects* and *mental disorders*.

- 1) Birth defects. Accutane can cause birth defects (deformed babies) if taken by a pregnant woman.** It can also cause miscarriage (losing the baby before birth), premature (early) birth, or death of the baby. Do not take Accutane if you are pregnant or plan to become pregnant while you are taking Accutane. Do not get pregnant for 1 month after you stop taking Accutane. Also, if you get pregnant while taking Accutane, stop taking it right away and call your prescriber.

All females should read the section in this Medication Guide "What are the important warnings for females taking Accutane?"

- 2) Mental problems and suicide.** Some patients, while taking Accutane or soon after stopping Accutane, have become depressed or developed other serious mental problems. Symptoms of these problems include sad, "anxious" or empty mood, irritability, anger, loss of pleasure or interest in social or sports activities, sleeping too much or too little, changes in weight or appetite, school or work performance going down, or trouble concentrating. Some patients taking Accutane have had thoughts about hurting themselves or putting an end to their own lives (suicidal thoughts). Some people tried to end their own lives. And some people have ended their own lives. There were reports that some of these people did not appear depressed. There have been reports of patients on Accutane becoming aggressive or violent. No one knows if Accutane caused these behaviors or if they would have happened even if the person did not take Accutane.

All patients should read the section in this Medication Guide "What are the signs of mental problems?"

For other possible serious side effects of Accutane, see "What are the possible side effects of Accutane?" in this Medication Guide.

What are the important warnings for females taking Accutane?

You must not become pregnant while taking Accutane, or for 1 month after you stop taking Accutane. Accutane can cause severe birth defects in babies of women who take it while they are pregnant, even if they take Accutane for only a short time. **There is an extremely high risk that**

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MOST IMPORTANT INFORMATION

What is the most important information I should know about Accutane?

Accutane is used to treat a type of severe acne (nodular acne) that has not been helped by other treatments, including antibiotics. However, Accutane can cause serious side effects. Before starting Accutane, discuss with your prescriber how bad your acne is, the possible benefits of Accutane, and its possible side effects, to decide if Accutane is right for you. Your prescriber will ask you to read and sign a form or forms indicating you understand some of the serious risks of Accutane.

Possible serious side effects of Accutane include *birth defects* and *mental disorders*.

1) Birth Defects

If taken by a pregnant woman, Accutane can cause:

- birth defects (deformed babies)
- miscarriage (losing the baby before birth)
- premature (early) birth
- death of the baby

Do not take Accutane if you are pregnant or plan to become pregnant while you are taking Accutane. Do not get pregnant for 1 month after you stop taking Accutane. Also, if you get pregnant while taking Accutane, stop taking it right away and call your prescriber.

All females should read the section "Warnings for Females."

2) Mental problems and suicide

Some patients have become depressed or developed other serious mental problems. This happened while taking Accutane or soon after stopping Accutane. Symptoms of mental problems include:

- sad mood
- anxious mood
- empty mood
- irritability
- anger
- aggression
- violence
- sleep too much
- sleep too little
- changes in weight
- changes in appetite
- lose interest in:
- social activities
- sports activities
- school/work performance problems
- trouble concentrating
- thoughts of hurting self
- suicidal thoughts (ending own life)
- try suicide
- commit suicide (*may not seem depressed*)

No one knows if Accutane caused these behaviors or if they would have happened even if the person did not take Accutane.

All patients should read the section "Mental Problems."

For other possible serious side effects of Accutane, see "Side Effects" in this Medication Guide.

- Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
- Have a change in your appetite or body weight
- Have trouble concentrating
- Withdraw from your friends or family
- Feel like you have no energy
- Have feelings of worthlessness or inappropriate guilt
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts)

What is Accutane?

Accutane is used to treat the most severe form of acne (nodular acne) that cannot be cleared up by any other acne treatments, including antibiotics. In severe nodular acne, many red, swollen, tender lumps form in the skin. These can be the size of pencil erasers or larger. If untreated, nodular acne can lead to permanent scars. However, because Accutane can have serious side effects, you should talk with your prescriber about all of the possible treatments for your acne, and whether Accutane's possible benefits outweigh its possible risks.

Who should not take Accutane?

- **Do not take Accutane if you are pregnant, plan to become pregnant, or become pregnant during Accutane treatment.** Accutane causes severe birth defects. All females should read the section "What are the important warnings for females taking Accutane?" for more information and warnings about Accutane and pregnancy.
- Do not take Accutane unless you completely understand its possible risks and are willing to follow all of the instructions in this Medication Guide.

Tell your prescriber if you or someone in your family has had any kind of mental problems, asthma, liver disease, diabetes, heart disease, osteoporosis (bone loss), weak bones, anorexia nervosa (an eating disorder where people eat too little), or any other important health problems. Tell your prescriber about any food or drug allergies you have had in the past. These problems do not necessarily mean you cannot take Accutane, but your prescriber needs this information to discuss if Accutane is right for you.

How should I take Accutane?

- You will get no more than a 30-day supply of Accutane at a time, to be sure you check in with your prescriber each month to discuss side effects.
- Your prescription should have a special yellow self-adhesive sticker attached to it. The sticker is YELLOW. If your prescription does not have this yellow self-adhesive sticker, call your prescriber. The pharmacy should not fill your prescription unless it has the yellow self-adhesive sticker.

MENTAL PROBLEMS

What are the signs of mental problems?

Tell your prescriber if, to the best of your knowledge, you or someone in your family has ever had any mental illness, including

- depression
- suicidal behavior,
- psychosis (loss of contact with reality, such as hearing voices or seeing things that are not there)

Also, tell your prescriber if you take medicines for any of these problems.

Stop using Accutane and tell your provider right away if you:

- Feel sad
- Have crying spells
- Lose interest in activities you once enjoyed
- Sleep too much
- Have trouble sleeping
- Become more
 - irritable
 - angry
 - aggressive
- Have
 - temper outbursts
 - thoughts of violence
 - change in appetite
 - change in body weight
 - trouble concentrating
- Withdraw from your friends or family
- Have feelings of
 - no energy
 - worthlessness
 - inappropriate guilt
- Have thoughts about
 - hurting yourself
 - taking your own life (suicidal thoughts)

ABOUT ACCUTANE

What is Accutane?

Accutane is used to treat the most severe form of acne (nodular acne) that cannot be cleared up by any other acne treatments, including antibiotics. In severe nodular acne, many red, swollen, tender lumps form in the skin. These can be the size of pencil erasers or larger. If untreated, nodular acne can lead to permanent scars. However, because Accutane can have serious side effects, you should talk with your prescriber about all of the possible treatments for your acne, and whether Accutane's possible benefits outweigh its possible risks.

Does it make
a difference?

LEAFLET SECTIONS

LEAFLET SECTIONS

*“The leaflet is divided into several major sections.
What are the titles of the sections?”*

LEAFLET SECTIONS

*“The leaflet is divided into several major sections.
What are the titles of the sections?”*

Why is this interesting?

LEAFLET SECTIONS

*“The leaflet is divided into several major sections.
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Why is this interesting?

--Do they know what's in the document?

LEAFLET SECTIONS

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Why is this interesting?

--Do they know what's in the document?

--Would they look for info if needed later?

LEAFLET SECTIONS

*“The leaflet is divided into several major sections.
What are the titles of the sections?”*

Why is this interesting?

- Do they know what's in the document?
- Would they look for info if needed later?
- Where would they look for it?

LEAFLET SECTIONS

*“The leaflet is divided into several major sections.
What are the titles of the sections?”*

**Serious
Side Effects**

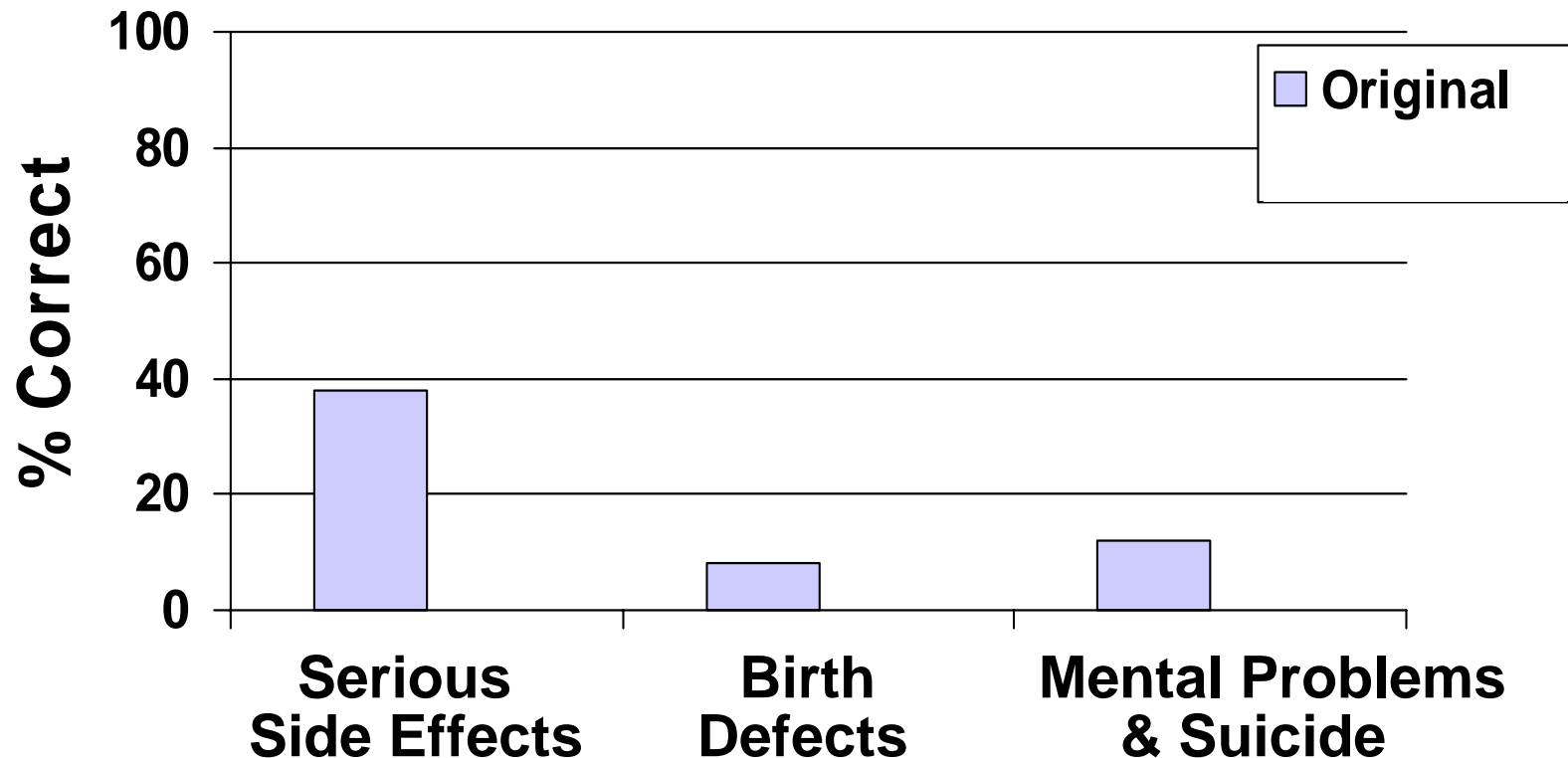
**Birth
Defects**

**Mental Problems
& Suicide**

“Most Important Information”

LEAFLET SECTIONS

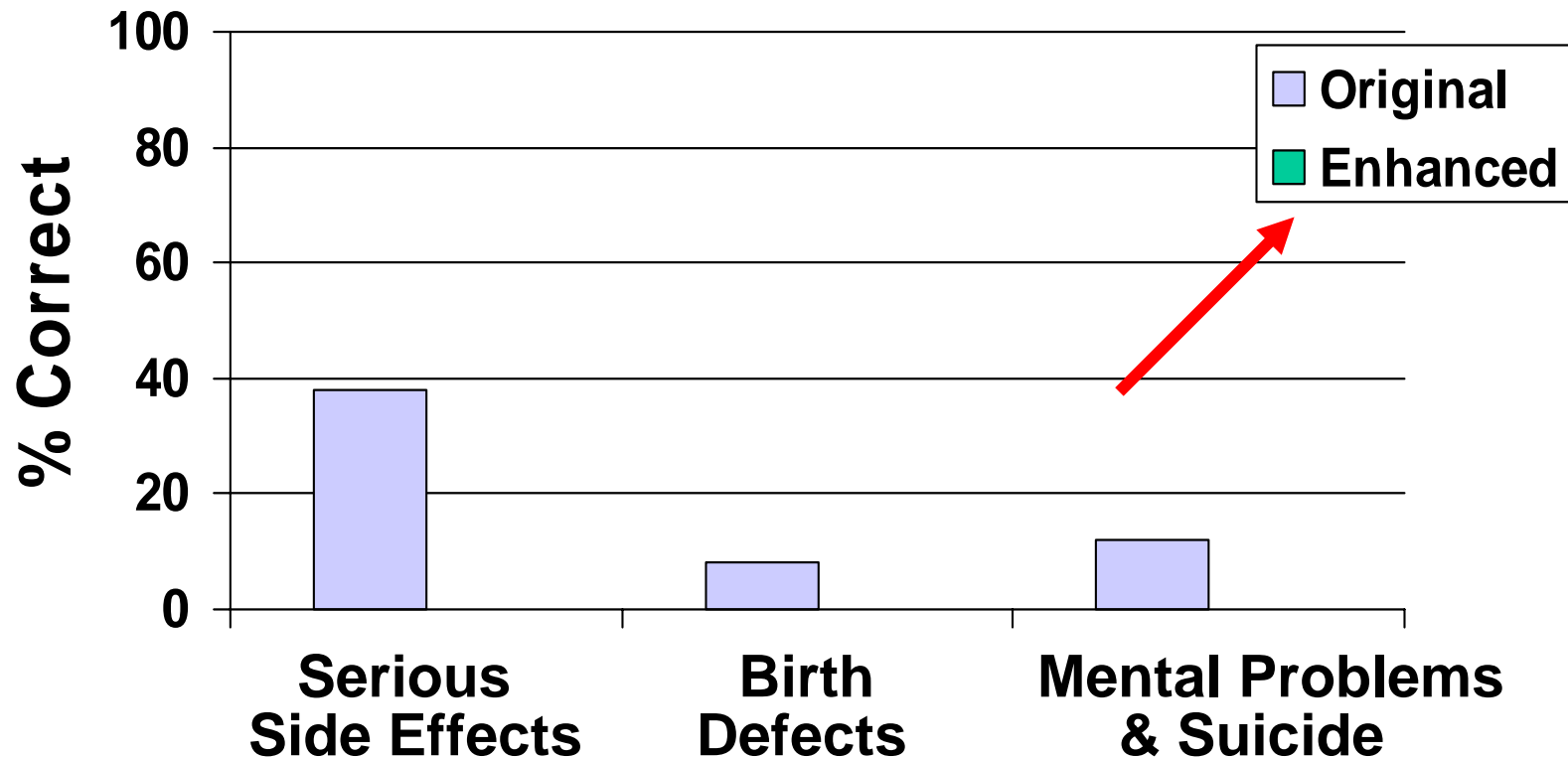
“The leaflet is divided into several major sections. What are the titles of the sections?”



“Most Important Information”

LEAFLET SECTIONS

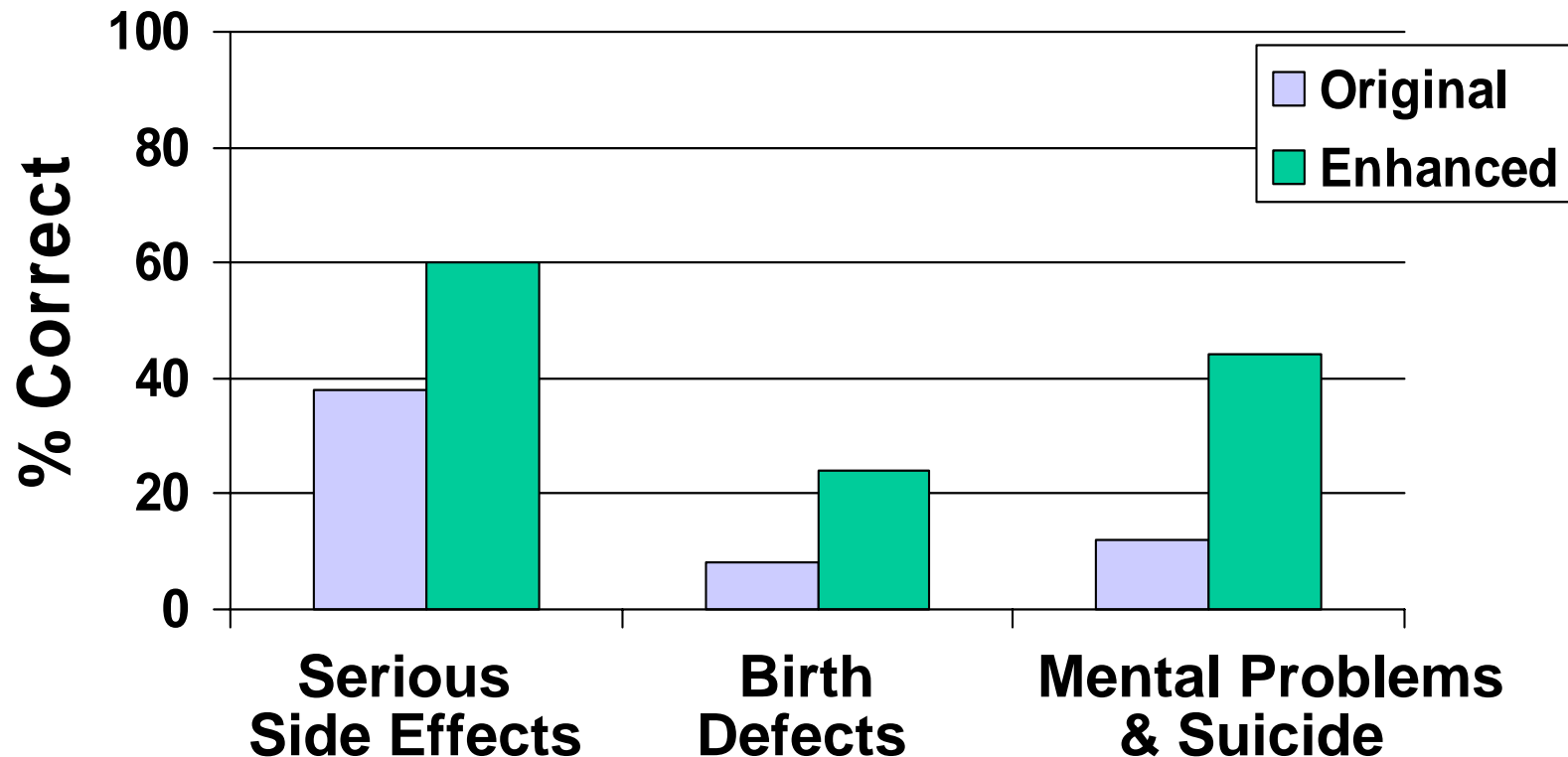
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“Most Important Information”

LEAFLET SECTIONS

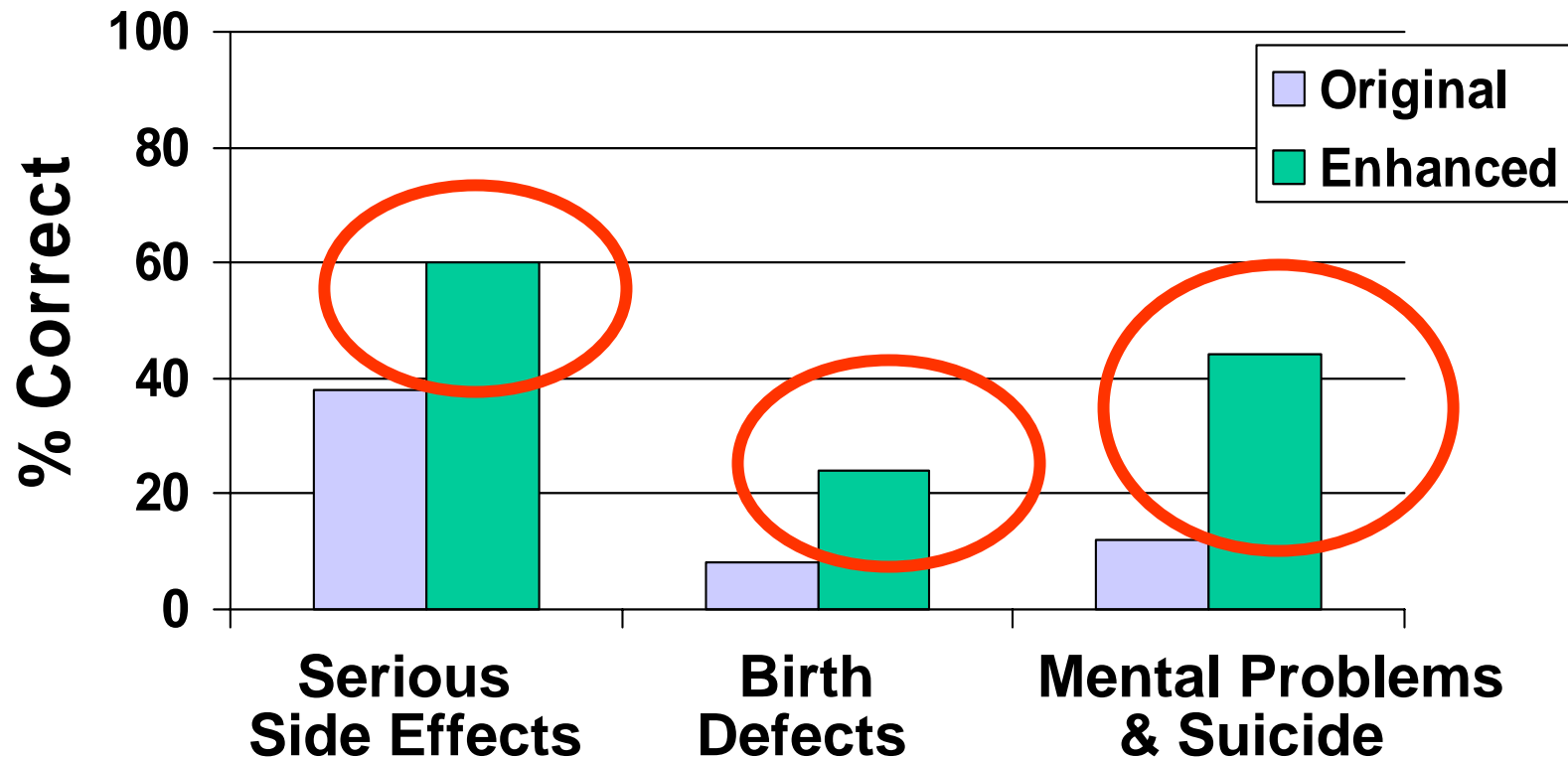
“The leaflet is divided into several major sections. What are the titles of the sections?”



“Most Important Information”

LEAFLET SECTIONS

“The leaflet is divided into several major sections. What are the titles of the sections?”



“Most Important Information”

TEST - ReTEST

Basic Methods

time



Study

Test

--Entire
document

--All content

--Original
Rep

Basic Methods

time →

Study

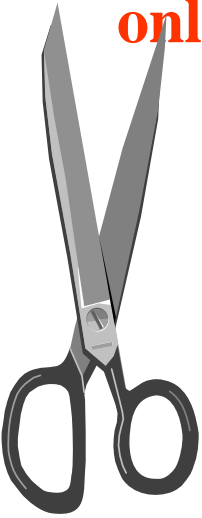
Test

Re-Test
Study Test

--Entire document
--Original Rep

--All content

--Side effects only



Basic Methods

time →

Study

Test

Re-Test

Study **Test**

--Entire document
--Original Rep

--All content

--Side effects only
or
Original **Enhanced**

Basic Methods

time →

Study

Test

Re-Test
Study **Test**

--Entire document
--Original Rep

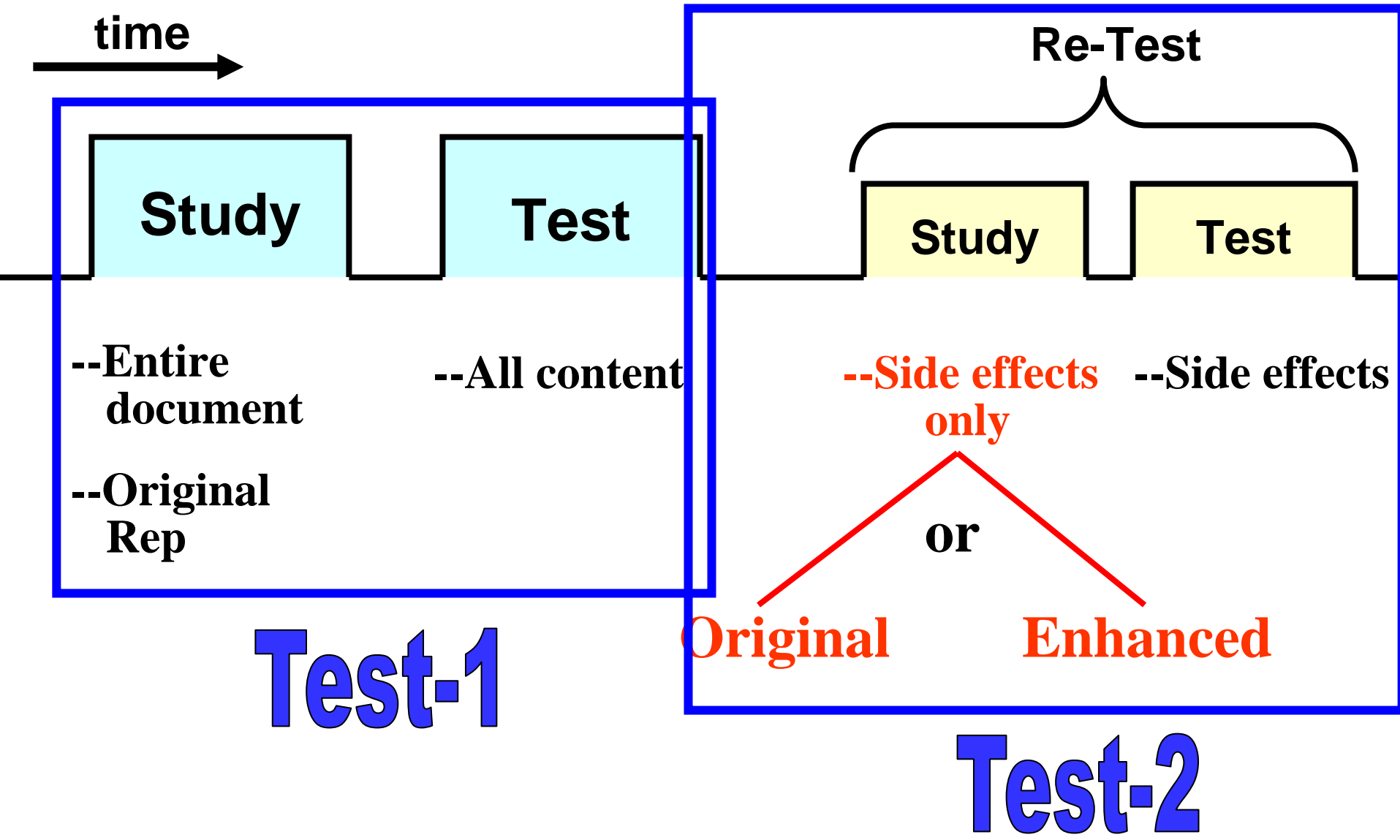
--All content

--Side effects only

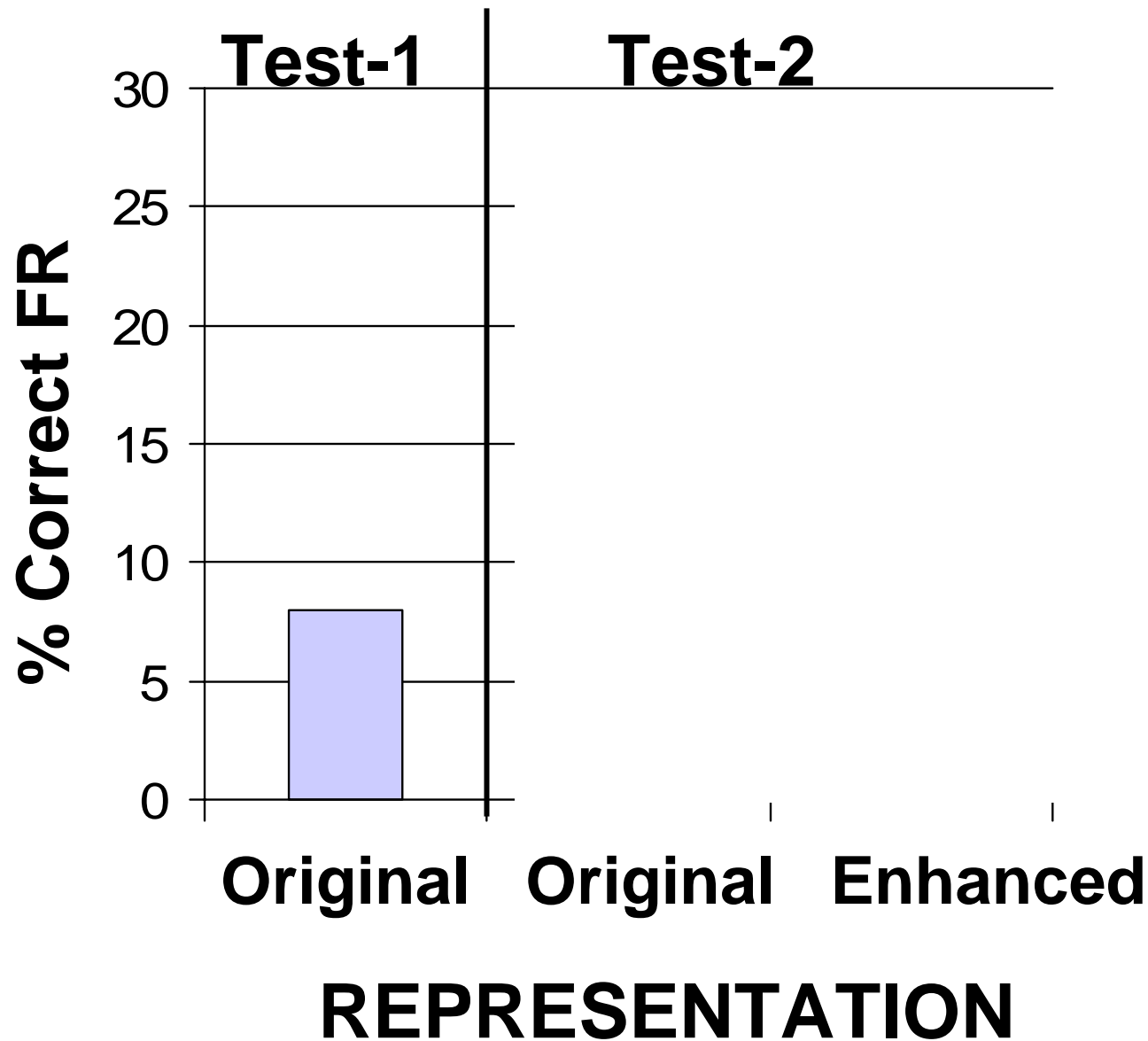
--Side effects

or
Original **Enhanced**

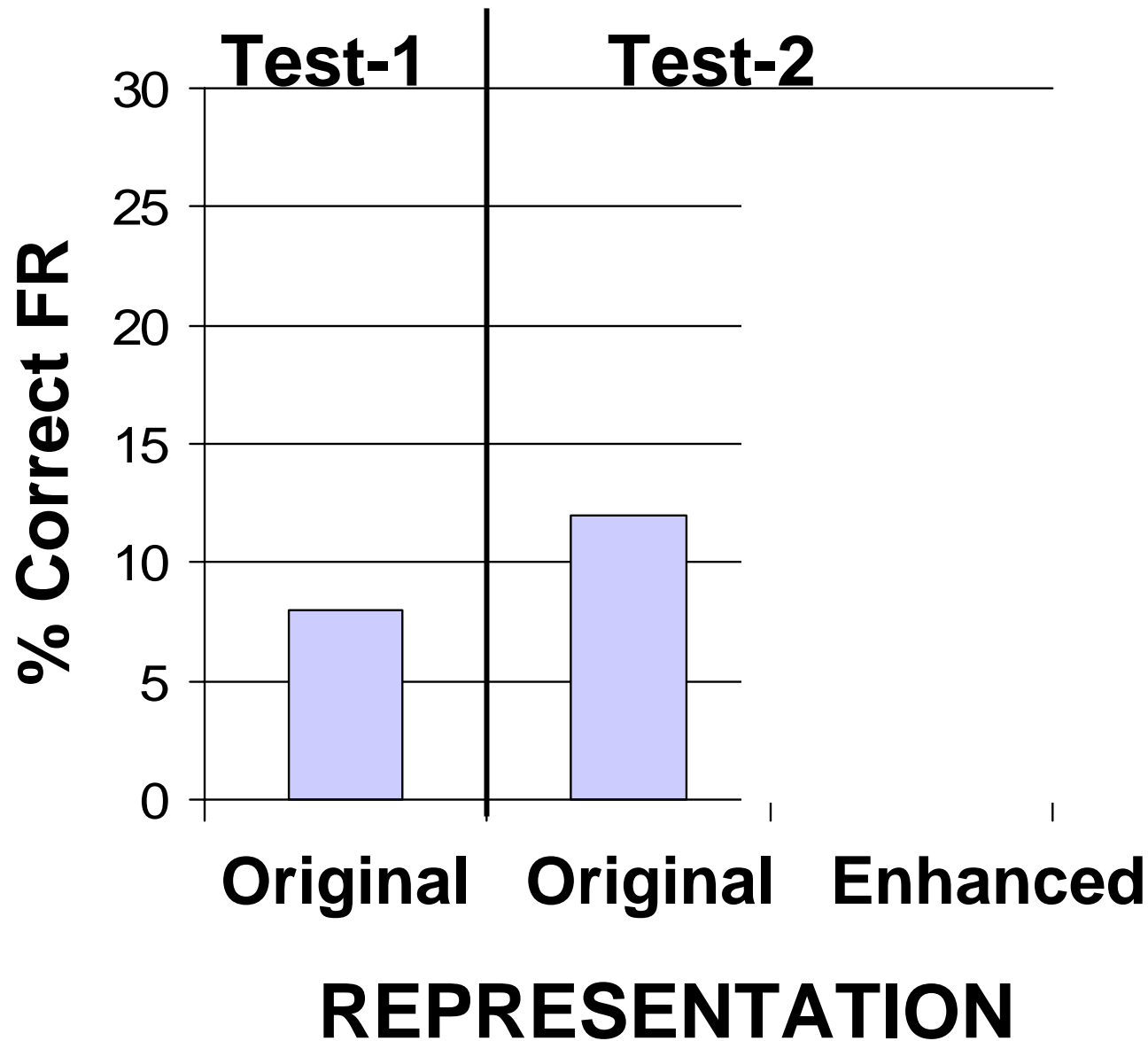
Basic Methods



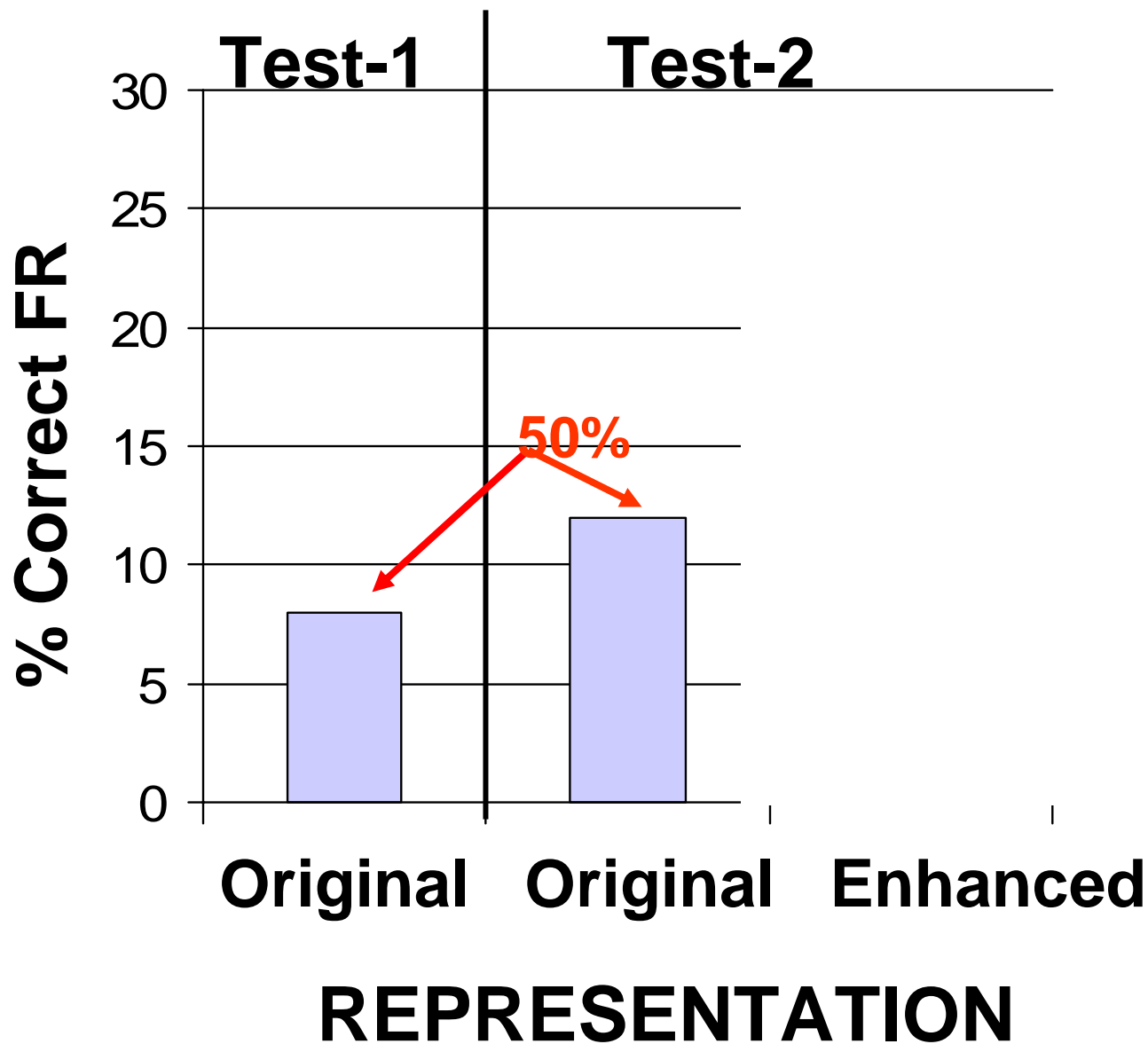
SIDE EFFECTS: ReTest



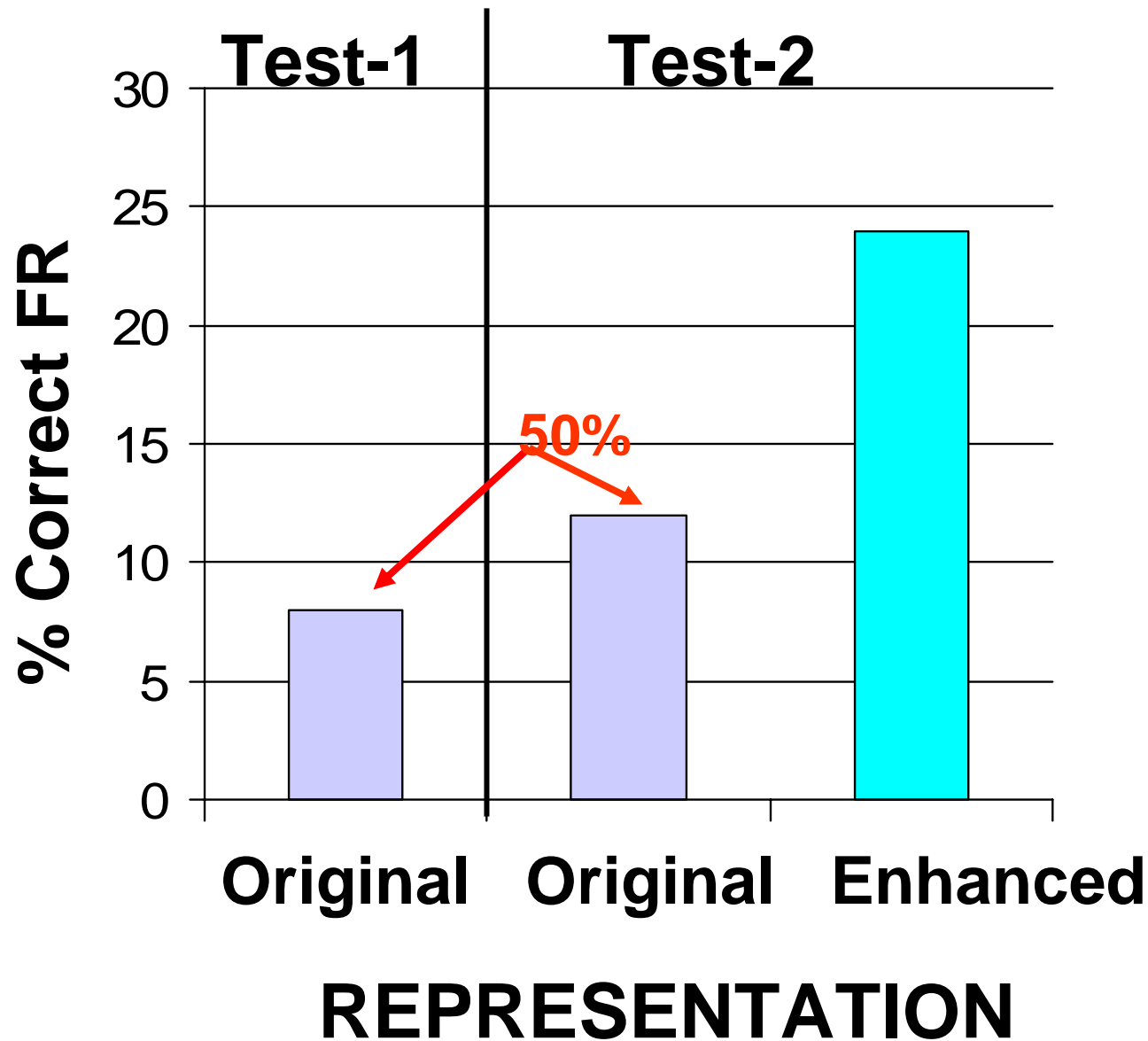
SIDE EFFECTS: ReTest



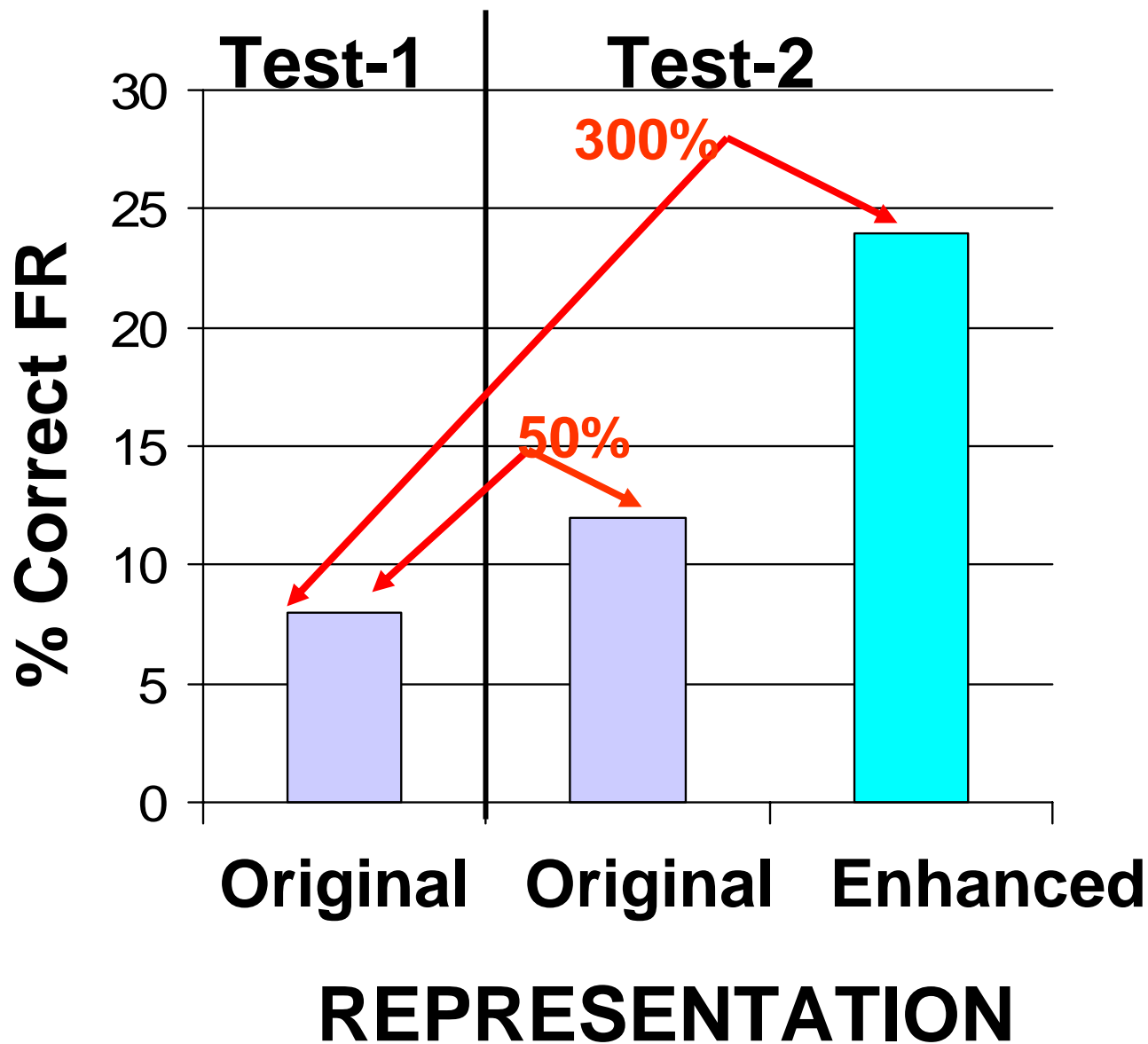
SIDE EFFECTS: ReTest



SIDE EFFECTS: ReTest



SIDE EFFECTS: ReTest



Results

Reported 2004, 2005,

Results

Reported 2004, 2005,

**New version of
Accutane Medication Guide**



AC CUTANE® Capsules (isotretinoin)

Read this Medication Guide every time you get a prescription or a refill for Accutane (ACK-u-tane). There may be new information. This information does not take the place of talking with your prescriber (doctor or other health care provider).

What is the most important information I should know about Accutane?

Accutane is used to treat a type of severe acne (nodular acne) that has not been helped by treatments, including antibiotics. However, Accutane can cause serious side effects. Before starting Accutane, discuss with your prescriber how bad your acne is, the possible benefit: Accutane, and its possible side effects, to decide if Accutane is right for you. Your prescriber will ask you to read and sign a form or forms indicating you understand some of the serious side effects of Accutane.

Possible serious side effects of taking Accutane include birth defects and mental disorders.

1. **Birth defects. Accutane can cause birth defects (deformed babies) if taken by a pregnant woman.** It can also cause miscarriage (losing the baby before birth), preterm (early) birth, or death of the baby. Do not take Accutane if you are pregnant or plan to become pregnant while you are taking Accutane. Do not get pregnant for 1 month after stopping taking Accutane. Also, if you get pregnant while taking Accutane, stop taking it right away and call your prescriber.

All females should read the section in this Medication Guide "What are the important warnings for females taking Accutane?"

2. **Mental problems and suicide.** Some patients, while taking Accutane or soon after stopping taking Accutane, have become depressed or developed other serious mental problems. Symptoms of these problems include sad, "anxious" or empty mood, irritability, anger, loss of interest in social or sports activities, sleeping too much or too little, changes in weight, loss of appetite, school or work performance going down, or trouble concentrating. Some patients taking Accutane have had thoughts about hurting themselves or putting an end to their lives (suicidal thoughts). Some people tried to end their own lives. And some people have ended their own lives. There were reports that some of these people did not appear depressed. There have been reports of patients on Accutane becoming aggressive or violent. No one knows if Accutane caused these behaviors or if they would have happened even if the patient did not take Accutane.

All patients should read the section in this Medication Guide "What are the signs of mental problems?"

For other possible serious side effects of Accutane, see "What are the possible side effects of Accutane?" in this Medication Guide.

What are the important warnings for females taking Accutane?

You must not become pregnant while taking Accutane, or for 1 month after you stop taking Accutane. Accutane can cause severe birth defects in babies of women who take it while pregnant, even if they take Accutane for only a short time. **There is an extremely high risk**



AC CUTANE (ACK-U-TANE)

(isotretinoin capsules)

Read the Medication Guide that comes with Accutane before you start taking it and each time you get a prescription. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about Accutane?

- Accutane is used to treat a type of severe acne (nodular acne) that has not been helped by other treatments, including antibiotics.
- Because Accutane can cause birth defects, Accutane is only for patients who can understand and agree to carry out all of the instructions in the iPLEDGE program.
- Accutane may cause serious mental health problems.

1. **Birth defects (deformed babies), loss of a baby before birth (miscarriage), death of the baby, and early (premature) births.** Female patients who are pregnant or who plan to become pregnant must not take Accutane. **Female patients must not get pregnant:**

- for 1 month before starting Accutane
- while taking Accutane
- for 1 month after stopping Accutane.

If you get pregnant while taking Accutane, stop taking it right away and call your doctor. Doctors and patients should report all cases of pregnancy to:

- FDA MedWatch at 1-800-FDA-1088, and
- the iPLEDGE pregnancy registry at 1-800-495-0654

2. **Serious mental health problems.** Accutane may cause:

- **depression**
- **psychosis** (seeing or hearing things that are not real)
- **suicide.** Some patients taking Accutane have had thoughts about hurting themselves or putting an end to their own lives (suicidal thoughts). Some people tried to end their own lives. And some people have ended their own lives.

your baby will be deformed or will die if you are pregnant while taking Accutane. Taking Accutane also increases the chance of miscarriage and premature births.

Female patients will not get their first prescription for Accutane unless there is proof they had 2 negative pregnancy tests. The first test must be done when your prescriber decides to prescribe Accutane. The second pregnancy test must be done during the first 5 days of the menstrual period right before starting Accutane therapy, or as instructed by your prescriber. At the end of each month of treatment, you must have a negative result from a urine or serum pregnancy test. Female patients cannot get another prescription for Accutane unless there is proof that they had a negative pregnancy test.

A yellow self-adhesive Accutane Qualification Sticker on your prescription indicates to the pharmacist that you are qualified by your prescriber to get Accutane.

While you are taking Accutane, you **must** use effective birth control. **You must use 2 separate effective forms of birth control at the same time** for at least 1 month before starting Accutane, while you take it, and for 1 month after you stop taking it. You can either discuss effective birth control methods with your prescriber or go for a free visit to discuss birth control with another physician or family planning expert. Your prescriber can arrange this free visit, which will be paid for by the manufacturer.

You must use 2 separate forms of effective birth control because any method, including birth control pills and sterilization, can fail. There are only 2 reasons you would not need separate methods of effective birth control:

1. You have had your womb removed by surgery (a hysterectomy).
2. You are absolutely certain you will not have genital-to-genital sexual contact with a partner before, during, and for 1 month after Accutane treatment.

If you have sex at any time without using 2 forms of effective birth control, get pregnant, miss your period, stop using Accutane and call your prescriber right away.

All patients should read the rest of this Medication Guide.

What are the signs of mental problems?

Tell your prescriber if, to the best of your knowledge, you or someone in your family has ever had any mental illness, including depression, suicidal behavior, or psychosis. Psychosis is a loss of contact with reality, such as hearing voices or seeing things that are not there. Also tell your prescriber if you take medicines for any of these problems.

Stop using Accutane and tell your provider right away if you:

- Start to feel sad or have crying spells
- Lose interest in activities you once enjoyed
- Sleep too much or have trouble sleeping

Stop Accutane and call your doctor right away if you or a family member notices that you have any of the following signs and symptoms of depression or psychosis:

- start to feel sad or have crying spells
- lose interest in activities you once enjoyed
- sleep too much or have trouble sleeping
- become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
- have a change in your appetite or body weight
- have trouble concentrating
- withdraw from your friends or family
- feel like you have no energy
- have feelings of worthlessness or guilt
- start having thoughts about hurting yourself or taking your own life (suicidal thoughts)
- start acting on dangerous impulses
- start seeing or hearing things that are not real

After stopping Accutane, you may also need follow-up mental health care if you had any of these symptoms.

What is Accutane?

Accutane is a medicine taken by mouth to treat the most severe form of acne (nodular acne) that cannot be cleared up by any other acne treatments, including antibiotics. Accutane can cause serious side effects (see **“What is the most important information I should know about Accutane?”**). Accutane can only be:

- prescribed by doctors that are registered in the iPLEDGE program
- dispensed by a pharmacy that is registered with the iPLEDGE program
- given to patients who are registered in the iPLEDGE program and agree to do everything required in the program

What is severe nodular acne?

Severe nodular acne is when many red, swollen, tender lumps form in the skin. These can be the size of pencil erasers or larger. If untreated, nodular acne can lead to permanent scars.

Who should not take Accutane?

- **Do not take Accutane if you are pregnant, plan to become pregnant, or become pregnant during Accutane treatment.** Accutane causes severe birth defects. See **“What is the most important information I should know about Accutane?”**

- Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
- Have a change in your appetite or body weight
- Have trouble concentrating
- Withdraw from your friends or family
- Feel like you have no energy
- Have feelings of worthlessness or inappropriate guilt
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts)

What is Accutane?

Accutane is used to treat the most severe form of acne (nodular acne) that cannot be cleared up by any other acne treatments, including antibiotics. In severe nodular acne, many red, swollen, tender lumps form in the skin. These can be the size of pencil erasers or larger. If untreated, nodular acne can lead to permanent scars. However, because Accutane can have serious side effects, you should talk with your prescriber about all of the possible treatments for your acne, and whether Accutane's possible benefits outweigh its possible risks.

Who should not take Accutane?

- **Do not take Accutane if you are pregnant, plan to become pregnant, or become pregnant during Accutane treatment.** Accutane causes severe birth defects. All females should read the section "What are the important warnings for females taking Accutane?" for more information and warnings about Accutane and pregnancy.
- Do not take Accutane unless you completely understand its possible risks and are willing to follow all of the instructions in this Medication Guide.

Tell your prescriber if you or someone in your family has had any kind of mental problems, asthma, liver disease, diabetes, heart disease, osteoporosis (bone loss), weak bones, anorexia nervosa (an eating disorder where people eat too little), or any other important health problems. Tell your prescriber about any food or drug allergies you have had in the past. These problems do not necessarily mean you cannot take Accutane, but your prescriber needs this information to discuss if Accutane is right for you.

How should I take Accutane?

- You will get no more than a 30-day supply of Accutane at a time, to be sure you check in with your prescriber each month to discuss side effects.
- Your prescription should have a special yellow self-adhesive sticker attached to it. The sticker is YELLOW. If your prescription does not have this yellow self-adhesive sticker, call your prescriber. The pharmacy should not fill your prescription unless it has the yellow self-adhesive sticker.

How should I take Accutane?

- You must take Accutane exactly as prescribed. You must also follow all the instructions of the iPLEDGE program. Before prescribing Accutane, your doctor will:
 - explain the iPLEDGE program to you
 - have you sign the Patient Information/Informed Consent (for all patients). Female patients who can get pregnant must also sign another consent form.

You will not be prescribed Accutane if you can not agree to or follow all the instructions of the iPLEDGE program.

- You will get no more than a 30-day supply of Accutane at a time. This is to make sure you are following the Accutane iPLEDGE program. You should talk with your doctor each month about side effects.
- The amount of Accutane you take has been specially chosen for you. It is based on your body weight, and may change during treatment.
- Take Accutane 2 times a day with a meal, unless your doctor tells you otherwise. **Swallow your Accutane capsules whole with a full glass of liquid. Do not chew or suck on the capsule.** Accutane can hurt the tube that connects your mouth to your stomach (esophagus) if it is not swallowed whole.
- If you miss a dose, just skip that dose. **Do not take 2 doses at the same time.**
- If you take too much Accutane or overdose, call your doctor or poison control center right away.
- Your acne may get worse when you first start taking Accutane. This should last only a short while. Talk with your doctor if this is a problem for you.
- You must return to your doctor as directed to make sure you don't have signs of serious side effects. Your doctor may do blood tests to check for serious side effects from Accutane. Female patients who can get pregnant will get a pregnancy test each month.
- Female patients who can become pregnant must agree to use 2 separate forms of effective birth control at the same time 1 month before, while taking, and for 1 month after taking Accutane. **You must access the iPLEDGE system to answer questions about the program requirements and to enter your 2 chosen forms of birth control.** To access the iPLEDGE system, go to www.ipledgeprogram.com or call 1-866-495-0654.

You must talk about effective birth control methods with your doctor or go for a free visit to talk about birth control with another doctor or family planning

Low Visual Distinctiveness

Lab

06/20/02

MEDICATION GUIDE FOR ALL PATIENTS

ACCUTANE® Capsules (isotretinoin)

Read this Medication Guide every time you get a prescription or a refill for Accutane (ACK-u-tane). There may be new information. This information does not take the place of talking with your prescriber (doctor or other health care provider).

What is the most important information I should know about Accutane?

Accutane is used to treat a type of severe acne (nodular acne) that has not been helped by other treatments, including antibiotics. However, Accutane can cause serious side effects. Before starting Accutane, discuss with your prescriber how bad your acne is, the possible benefits of Accutane, and its possible side effects, to decide if Accutane is right for you. Your prescriber will ask you to read and sign a form or forms indicating you understand some of the serious risks of Accutane.

Possible serious side effects of taking Accutane include *birth defects* and *mental disorders*.

1. **Birth defects.** Accutane can cause birth defects (deformed babies) if taken by a pregnant woman. It can also cause miscarriage (losing the baby before birth), premature (early) birth, or death of the baby. Do not take Accutane if you are pregnant or plan to become pregnant while you are taking Accutane. Do not get pregnant for 1 month after you stop taking Accutane. Also, if you get pregnant while taking Accutane, stop taking it right away and call your prescriber.

All females should read the section in this Medication Guide "What are the important warnings for females taking Accutane?"

2. **Mental problems and suicide.** Some patients, while taking Accutane or soon after stopping Accutane, have become depressed or developed other serious mental problems. Symptoms of these problems include sad, "anxious" or empty mood, irritability, anger, loss of pleasure or interest in social or sports activities, sleeping too much or too little, changes in weight or appetite, school or work performance going down, or trouble concentrating. Some patients taking Accutane have had thoughts about hurting themselves or putting an end to their own lives (suicidal thoughts). Some people tried to end their own lives. And some people have ended their own lives. There were reports that some of these people did not appear depressed. There have been reports of patients on Accutane becoming aggressive or violent. No one knows if Accutane caused these behaviors or if they would have happened even if the person did not take Accutane.

All patients should read the section in this Medication Guide "What are the signs of mental problems?"

For other possible serious side effects of Accutane, see "What are the possible side effects of Accutane?" in this Medication Guide.

What are the important warnings for females taking Accutane?

You must not become pregnant while taking Accutane, or for 1 month after you stop taking Accutane. Accutane can cause severe birth defects in babies of women who take it while they are pregnant, even if they take Accutane for only a short time. **There is an extremely high risk that**

- The amount of Accutane you take has been specially chosen for you and may change during treatment.
- You will take Accutane 2 times a day with a meal, unless your prescriber tells you otherwise. Swallow your Accutane capsules with a full glass of liquid. This will help prevent the medication inside the capsule from irritating the lining of your esophagus (connection between mouth and stomach). For the same reason, do not chew or suck on the capsule.
- If you miss a dose, just skip that dose. Do not take 2 doses the next time.
- You should return to your prescriber as directed to make sure you don't have signs of serious side effects. Because some of Accutane's serious side effects show up in blood tests, some of these visits may involve blood tests (monthly visits for female patients should always include a urine or serum pregnancy test).

What should I avoid while taking Accutane?

- **Do not get pregnant** while taking Accutane. See "What is the most important information I should know about Accutane?" and "What are the important warnings for females taking Accutane?"
- **Do not breast feed** while taking Accutane and for 1 month after stopping Accutane. We do not know if Accutane can pass through your milk and harm the baby.
- **Do not give blood** while you take Accutane and for 1 month after stopping Accutane. If someone who is pregnant gets your donated blood, her baby may be exposed to Accutane and may be born with birth defects.
- **Do not take vitamin A supplements.** Vitamin A in high doses has many of the same side effects as Accutane. Taking both together may increase your chance of getting side effects.
- **Do not have cosmetic procedures to smooth your skin, including waxing, dermabrasion, or laser procedures, while you are using Accutane and for at least 6 months after you stop.** Accutane can increase your chance of scarring from these procedures. Check with your prescriber for advice about when you can have cosmetic procedures.
- **Avoid sunlight and ultraviolet lights** as much as possible. Tanning machines use ultraviolet lights. Accutane may make your skin more sensitive to light.
- **Do not use birth control pills that do not contain estrogen ("minipills").** They may not work while you take Accutane. Ask your prescriber or pharmacist if you are not sure what type you are using.
- **Talk with your doctor if you plan to take other drugs or herbal products.** This is especially important for patients using birth control pills and other hormonal types of birth control because the birth control may not work as effectively if you are taking certain drugs.

your baby will be deformed or will die if you are pregnant while taking Accutane. Taking Accutane also increases the chance of miscarriage and premature births.

Female patients will not get their first prescription for Accutane unless there is proof they have had 2 negative pregnancy tests. The first test must be done when your prescriber decides to prescribe Accutane. The second pregnancy test must be done during the first 5 days of the menstrual period right before starting Accutane therapy, or as instructed by your prescriber. Each month of treatment, you must have a negative result from a urine or serum pregnancy test. Female patients cannot get another prescription for Accutane unless there is proof that they have had a negative pregnancy test.

A yellow self-adhesive Accutane Qualification Sticker on your prescription indicates to the pharmacist that you are qualified by your prescriber to get Accutane.

While you are taking Accutane, you **must use effective birth control. You must use 2 separate effective forms of birth control at the same time** for at least 1 month before starting Accutane, while you take it, and for 1 month after you stop taking it. You can either discuss effective birth control methods with your prescriber or go for a free visit to discuss birth control with another physician or family planning expert. Your prescriber can arrange this free visit, which will be paid for by the manufacturer.

You must use 2 separate forms of effective birth control because any method, including birth control pills and sterilization, can fail. There are only 2 reasons you would not need to use 2 separate methods of effective birth control:

1. You have had your womb removed by surgery (a hysterectomy).
2. You are absolutely certain you will not have genital-to-genital sexual contact with a male before, during, and for 1 month after Accutane treatment.

If you have sex at any time without using 2 forms of effective birth control, get pregnant, or miss your period, stop using Accutane and call your prescriber right away.

All patients should read the rest of this Medication Guide.

What are the signs of mental problems?

Tell your prescriber if, to the best of your knowledge, you or someone in your family has ever had any mental illness, including depression, suicidal behavior, or psychosis. Psychosis means a loss of contact with reality, such as hearing voices or seeing things that are not there. Also, tell your prescriber if you take medicines for any of these problems.

Stop using Accutane and tell your provider right away if you:

- Start to feel sad or have crying spells
- Lose interest in activities you once enjoyed
- Sleep too much or have trouble sleeping

- or herbal products. You should not take the herbal supplement St. John's Wort because this herbal supplement may make birth control pills not work as effectively.

- **Talk with your doctor if you are currently taking an oral or injected corticosteroid or anticonvulsant (seizure) medication prior to using Accutane.** These drugs may weaken your bones.

- **Do not share Accutane with other people.** It can cause birth defects and other serious health problems.

- **Do not take Accutane with antibiotics unless you talk to your prescriber.** For some antibiotics, you may have to stop taking Accutane until the antibiotic treatment is finished. Use of both drugs together can increase the chances of getting increased pressure in the brain.

What are the possible side effects of Accutane?

Accutane has possible serious side effects

- **Accutane can cause birth defects, premature births, and death in babies** whose mothers took Accutane while they were pregnant. See "What is the most important information I should know about Accutane?" and "What are the important warnings for females taking Accutane?"
- **Serious mental health problems.** See "What is the most important information I should know about Accutane?"
- **Serious brain problems.** Accutane can increase the pressure in your brain. This can lead to permanent loss of sight, or in rare cases, death. Stop taking Accutane and call your prescriber right away if you get any of these signs of increased brain pressure: bad headache, blurred vision, dizziness, nausea, or vomiting. Also, some patients taking Accutane have had seizures (convulsions) or stroke.
- **Abdomen (stomach area) problems.** Certain symptoms may mean that your internal organs are being damaged. These organs include the liver, pancreas, bowel (intestines), and esophagus (connection between mouth and stomach). If your organs are damaged, they may not get better even after you stop taking Accutane. Stop taking Accutane and call your prescriber if you get severe stomach, chest or bowel pain, trouble swallowing or painful swallowing, new or worsening heartburn, diarrhea, rectal bleeding, yellowing of your skin or eyes, or dark urine.
- **Bone and muscle problems.** Accutane may affect bones, muscles, and ligaments and cause pain in your joints or muscles. Tell your prescriber if you plan vigorous physical activity during treatment with Accutane. Tell your prescriber if you develop pain, particularly back pain or joint pain. There are reports that some patients have had stunted growth after taking Accutane for acne as directed. There are also some reports of broken bones or reduced healing of broken bones after taking Accutane for acne as directed. No one knows if taking Accutane for acne will affect your bones. If you have a broken bone, tell your provider that

- Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
- Have a change in your appetite or body weight
- Have trouble concentrating
- Withdraw from your friends or family
- Feel like you have no energy
- Have feelings of worthlessness or inappropriate guilt
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts)

What is Accutane?

Accutane is used to treat the most severe form of acne (nodular acne) that cannot be swollen up by any other acne treatments, including antibiotics. In severe nodular acne, many red, swollen, tender lumps form in the skin. These can be the size of pencil erasers or larger. If untreated, nodular acne can lead to permanent scars. However, because Accutane can have serious side effects, you should talk with your prescriber about all of the possible treatments for your acne, and whether Accutane's possible benefits outweigh its possible risks.

Who should not take Accutane?

- **Do not take Accutane if you are pregnant, plan to become pregnant, or become pregnant during Accutane treatment.** Accutane causes severe birth defects. All females should read the section "What are the important warnings for females taking Accutane?" for more information and warnings about Accutane and pregnancy.

- Do not take Accutane unless you completely understand its possible risks and are willing to follow all of the instructions in this Medication Guide.

Tell your prescriber if you or someone in your family has had any kind of mental problems, asthma, liver disease, diabetes, heart disease, osteoporosis (bone loss), weak bones, anorexia nervosa (an eating disorder where people eat too little), or any other important health problems. Tell your prescriber about any food or drug allergies you have had in the past. These problems do not necessarily mean you cannot take Accutane, but your prescriber needs this information to discuss if Accutane is right for you.

How should I take Accutane?

- You will get no more than a 30-day supply of Accutane at a time, to be sure you check in with your prescriber each month to discuss side effects.
- Your prescription should have a special yellow self-adhesive sticker attached to it. The sticker is YELLOW. If your prescription does not have this yellow self-adhesive sticker, call your prescriber. The pharmacy should not fill your prescription unless it has the yellow self-adhesive sticker.

(Somewhat) Better Visual Distinctiveness

Now

MEDICATION GUIDE

ACCUTANE (ACK-U-TANE)

(isotretinoin capsules)

Read the Medication Guide that comes with Accutane before you start taking it and each time you get a prescription. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about Accutane?

- Accutane is used to treat a type of severe acne (nodular acne) that has not been helped by other treatments, including antibiotics.
- Because Accutane can cause birth defects, Accutane is only for patients who can understand and agree to carry out all of the instructions in the iPLEDGE program.
- Accutane may cause serious mental health problems.

1. Birth defects (deformed babies), loss of a baby before birth (miscarriage), death of the baby, and early (premature) births. Female patients who are pregnant or who plan to become pregnant must not take Accutane. Female patients must not get pregnant:

- for 1 month before starting Accutane
- while taking Accutane
- for 1 month after stopping Accutane.

If you get pregnant while taking Accutane, stop taking it right away and call your doctor. Doctors and patients should report all cases of pregnancy to:

- FDA MedWatch at 1-800-FDA-1088, and
- the iPLEDGE pregnancy registry at 1-800-495-0654

2. Serious mental health problems. Accutane may cause:

- depression
- psychosis (seeing or hearing things that are not real)
- suicide. Some patients taking Accutane have had thoughts about hurting themselves or putting an end to their own lives (suicidal thoughts). Some people tried to end their own lives. And some people have ended their own lives.

expert. Your doctor can arrange this free visit, which will be paid for by the company that makes Accutane.

If you have sex at any time without using 2 forms of effective birth control, get pregnant, or miss your expected period, stop using Accutane and call your doctor right away.

What should I avoid while taking Accutane?

- Do not get pregnant while taking Accutane and for 1 month after stopping Accutane. See "What is the most important information I should know about Accutane?"
- Do not breast feed while taking Accutane and for 1 month after stopping Accutane. We do not know if Accutane can pass through your milk and harm the baby.
- Do not give blood while you take Accutane and for 1 month after stopping Accutane. If someone who is pregnant gets your donated blood, her baby may be exposed to Accutane and may be born with birth defects.
- Do not take other medicines or herbal products with Accutane unless you talk to your doctor. See "What should I tell my doctor before taking Accutane?"
- Do not drive at night until you know if Accutane has affected your vision. Accutane may decrease your ability to see in the dark.
- Do not have cosmetic procedures to smooth your skin, including waxing, dermabrasion, or laser procedures, while you are using Accutane and for at least 6 months after you stop. Accutane can increase your chance of scarring from these procedures. Check with your doctor for advice about when you can have cosmetic procedures.
- Avoid sunlight and ultraviolet lights as much as possible. Tanning machines use ultraviolet lights. Accutane may make your skin more sensitive to light.
- Do not share Accutane with other people. It can cause birth defects and other serious health problems.

What are the possible side effects of Accutane?

- Accutane can cause birth defects (deformed babies), loss of a baby before birth (miscarriage), death of the baby, and early (premature) births. See "What is the most important information I should know about Accutane?"
- Accutane may cause serious mental health problems. See "What is the most important information I should know about Accutane?"

Stop Accutane and call your doctor right away if you or a family member notices that you have any of the following signs and symptoms of depression or psychosis:

- start to feel sad or have crying spells
- lose interest in activities you once enjoyed
- sleep too much or have trouble sleeping
- become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
- have a change in your appetite or body weight
- have trouble concentrating
- withdraw from your friends or family
- feel like you have no energy
- have feelings of worthlessness or guilt
- start having thoughts about hurting yourself or taking your own life (suicidal thoughts)
- start acting on dangerous impulses
- start seeing or hearing things that are not real

After stopping Accutane, you may also need follow-up mental health care if you had any of these symptoms.

What is Accutane?

Accutane is a medicine taken by mouth to treat the most severe form of acne (nodular acne) that cannot be cleared up by any other acne treatments, including antibiotics. Accutane can cause serious side effects (see "What is the most important information I should know about Accutane?"). Accutane can only be:

- prescribed by doctors that are registered in the iPLEDGE program
- dispensed by a pharmacy that is registered with the iPLEDGE program
- given to patients who are registered in the iPLEDGE program and agree to do everything required in the program

What is severe nodular acne?

Severe nodular acne is when many red, swollen, tender lumps form in the skin. These can be the size of pencil erasers or larger. If untreated, nodular acne can lead to permanent scars.

Who should not take Accutane?

- Do not take Accutane if you are pregnant, plan to become pregnant, or become pregnant during Accutane treatment. Accutane causes severe birth defects. See "What is the most important information I should know about Accutane?"
- serious brain problems. Accutane can increase the pressure in your brain. This can lead to permanent loss of eyesight and, in rare cases, death. Stop taking Accutane and call your doctor right away if you get any of these signs of increased brain pressure:
 - bad headache
 - blurred vision
 - dizziness
 - nausea, or vomiting
 - seizures (convulsions)
 - stroke
- stomach area (abdomen) problems. Certain symptoms may mean that your internal organs are being damaged. These organs include the liver, pancreas, bowel (intestines), and esophagus (connection between mouth and stomach). If your organs are damaged, they may not get better even after you stop taking Accutane. Stop taking Accutane and call your doctor if you get:
 - severe stomach, chest or bowel pain
 - trouble swallowing or painful swallowing
 - new or worsening heartburn
 - diarrhea
 - rectal bleeding
 - yellowing of your skin or eyes
 - dark urine
- bone and muscle problems. Accutane may affect bones, muscles, and ligaments and cause pain in your joints or muscles. Tell your doctor if you plan hard physical activity during treatment with Accutane. Tell your doctor if you get:
 - back pain
 - joint pain
 - broken bone. Tell all healthcare providers that you take Accutane if you break a bone.Stop Accutane and call your doctor right away if you have muscle weakness. Muscle weakness with or without pain can be a sign of serious muscle damage. Accutane may stop long bone growth in teenagers who are still growing.
- hearing problems. Stop using Accutane and call your doctor if your hearing gets worse or if you have ringing in your ears. Your hearing loss may be permanent.
- vision problems. Accutane may affect your ability to see in the dark. This condition usually clears up after you stop taking Accutane, but it may be permanent. Other serious eye effects can occur. Stop taking Accutane and call

How should I take Accutane?

- You must take Accutane exactly as prescribed. You must also follow all the instructions of the iPLEDGE program. Before prescribing Accutane, your doctor will:
 - explain the iPLEDGE program to you
 - have you sign the Patient Information/Informed Consent (for all patients). Female patients who can get pregnant must also sign another consent form.
- You will not be prescribed Accutane if you can not agree to or follow all the instructions of the iPLEDGE program.
- You will get no more than a 30-day supply of Accutane at a time. This is to make sure you are following the Accutane iPLEDGE program. You should talk with your doctor each month about side effects.
- The amount of Accutane you take has been specially chosen for you. It is based on your body weight, and may change during treatment.
- Take Accutane 2 times a day with a meal, unless your doctor tells you otherwise. Swallow your Accutane capsules whole with a full glass of liquid. Do not chew or suck on the capsule. Accutane can hurt the tube that connects your mouth to your stomach (esophagus) if it is not swallowed whole.
- If you miss a dose, just skip that dose. Do not take 2 doses at the same time.
- If you take too much Accutane or overdose, call your doctor or poison control center right away.
- Your acne may get worse when you first start taking Accutane. This should last only a short while. Talk with your doctor if this is a problem for you.
- You must return to your doctor as directed to make sure you don't have signs of serious side effects. Your doctor may do blood tests to check for serious side effects from Accutane. Female patients who can get pregnant will get a pregnancy test each month.
- Female patients who can become pregnant must agree to use 2 separate forms of effective birth control at the same time 1 month before, while taking, and for 1 month after taking Accutane. You must access the iPLEDGE system to answer questions about the program requirements and to enter your 2 forms of birth control. To access the iPLEDGE system, go to iprogram.com or call 1-866-495-0654. Talk about effective birth control methods with your doctor or go for a talk about birth control with another doctor or family planning

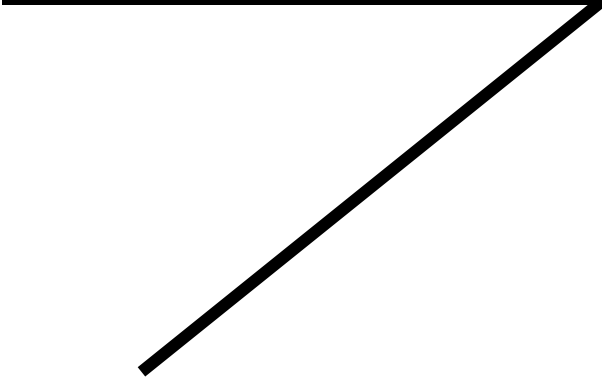
Other Findings

Other Findings



Conclusion

RISK INFORMATION



**Physically
present**

RISK INFORMATION

**Physically
present**

**Functionally
absent**

RISK INFORMATION

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graph TD; A["RISK INFORMATION"] --> B["Physically present"]; A --> C["Functionally USEFUL"]
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**Physically
present**

**Functionally
USEFUL**

RISK INFORMATION

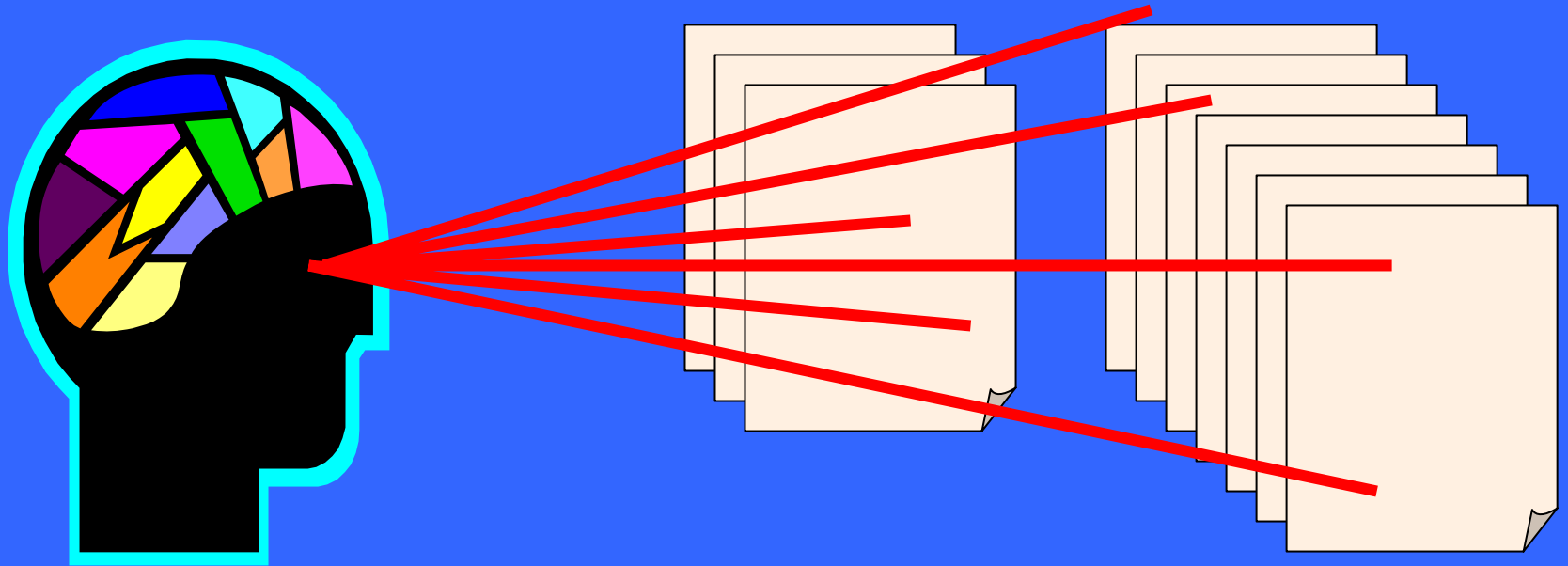
**Physically
present**

**Functionally
USEFUL**

Increase

Cognitive Accessibility

Mandatory Drug Risk Information: How much information is too much?



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<http://www.duke.edu/~ruthday/medcog.html>

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