

# Medicines In My Home



Department of Health and Human Services
Food and Drug Administration

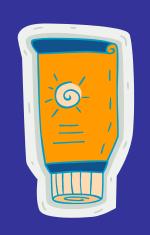
# Medicines are Drugs

## A medicine or drug...

- changes how your body works, or
- treats or prevents a disease or symptom

# Who Has Used an Over-the-Counter Medicine This Week?







What are some reasons for using an OTC medicine?

# Prescription and Over-the-Counter Medicines



How are they different?

How are they the same?

## Prescription and Over-the-Counter Medicines

How are they different? How are they the same?

## **Prescription**

- Ordered by a doctor
- 2. Bought at a pharmacy
- 3. Ordered for and used by only one person

## Both types of medicine:

- Directions must be followed carefully and correctly
- Children should use only with permission of a parent or guardian
- A pharmacist can answer questions

## **Over-the-Counter**

- Can buy without a doctor's order
- 2. Bought off the shelf in store aisles
- 3. May be used by more than one person for the same symptom or problem



# Important Medicine Rules

- Never share your prescription medicine with someone else.
- Never use someone else's prescription medicine.
- With OTC medicine, always check the dose.
  - The right dose for you may be different than for your friend or family member.



# How do you decide which medicine is the right OTC medicine for you?

# Read the Drug Facts label

All OTC medicines have a Drug Facts label

## Active Ingredients And what they do

# Drug Facts Label

#### Drug Facts

#### Active ingredients

#### Purposes

(in each 5 ml teaspoonful) lbuprofen 100 mg (NSAID)\*.

.....Pain reliever/ fever reducer

Pseudoephedrine HCl 15mg.....Nasal decongestant \*nonsteroidal anti-inflammatory drug

#### Uses temporarily relieves

- nasal and sinus congestion
- stuffy nose head ache
- sore throat
- minor body aches and pains
- fever

#### Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash bliste

Sore throat warning: Severe or persistent sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by a doctor.

#### Do not use

- if the child has ever had an allergic reaction to any other pain reliever/fever reducer and/or nasal decongestant
- right before or after heart surgery
- in a child who is taking a prescription monoamine oxidase inhibitor (MAOI), certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease, or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

#### Ask a doctor before use if the child has

- problems or serious side effects from taking pain relievers, fever reducers, or nasal decongestants
- stomach problems that last or come back, such as heartburn, upset stomach, or stomach pain
- ulcers
- bleeding problems
- not been drinking fluids
- lost a lot of fluid due to vomiting or diarrhea
- high blood pressure
- heart or kidney disease
- taken a diuretic

#### Ask a doctor or pharmacist before use if the child is

- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug
- under a doctor's care for any continuing medical condition
- taking any other drug

#### Drug Facts (continued)

#### When using this product

- take with food or milk if stomach upset occurs
- long term continuous use may increase the risk of heart attack or stroke

#### Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- the child does not get any relief during the first day (24 hours) of treatment
- fever, pain, or nasal congestion gets worse or lasts for more than 3 days
- stomach pain or upset gets worse or lasts
- symptoms continue or get worse
- redness or swelling is present in the painful area.
- the child gets nervous, dizzy, or sleepless
- any new symptoms appear

Keep out of reach of children. In case of overdose, get medical help or contact a Polson Control Center right away.

#### Directions

- this product does not contain directions or complete warnings for adult use
- do not give more than directed
- do not give longer than 10 days, unless directed by a doctor (see Warnings)
- shake well before using
- find right dose on chart below. If possible use weight to dose; otherwise use age.
- use only with enclosed measuring cup
- If needed, repeat dose every 6 hours
   do not use more than 4 times a day
- replace original bottle cap to maintáin child resistance
- wash dosage cup after each use Dosing Chart

Weight (lb)	Age (yrs)	Dose (teaspoonful)
under 24	under 2	ask a doctor
24-47	2 to 5	1 tsp
48-95	6 to 11	2 tsp

#### Other information

- do not use if printed neckband is broken or missing
- store at 15-30°C (59-86°F)
- see bottom of box for lot number and expiration

Inactive ingredients acesulfame potassium, ottric acid, corn syrup, D&C red #33, FDA&C blue #1, FD&C red #40, flavors, glycerin, hypromellose, polysorbate 80, purified water, sodium benzoate, xanthan gum

Questions? 1-800-123-4567 http://ChildrensFeelBetter.com

# Active Ingredients: The parts of the medicine that make it work.

What does Drug Facts tell us about each active ingredient ???

- Its name
- How much is in each pill or teaspoon (5 mL)
- What it does (its purpose or job)
- The problems it treats (its uses)

## What does this medicine treat?



Feel Better **Cold and Fever** 

Suspension



Ibuprofen Pain reliever/ (NSAID)

Fever reducer

Pseudoephedrine HCL▶ Nasal decongestant

Relieves: Fever. Sore Throat Stuffy Nose

Grape Flavor



### Drug Facts

#### Active ingredients Purposes

(in each 5 ml teaspoonful)

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- asthma (wheezing)
- shock
- skin reddening
- rash blisters

Sore throat warning: Severe or persistent sore throat accompanied by high fever , headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by a doctor.

## What does this medicine treat?





Grape Flavor



### Drug Facts

### Active ingredients

Purposas

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- stuffy nose
   head ache
- sore throat

fever

minor body aches and pains

### Warnings

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hives

- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
   blisters

Sore throat warning: Severe or persistent sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by a doctor.





## Children's Feel Better **Cold and Fever** Suspension

(NSAID)

Fever reducer

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Pseudoephedrine HCL> Nasal decongestant

Relieves: Fever. Sore Throat Stuffy Nose

Grape Flavor

## Drug Facts

### Active ingredients

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Pain reliever/ fever reducer

**Purposes** 

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#### **Uses** temporarily relieves

- nasal and sinus congestion
- stuffy nose
   head ache
- minor body aches and pains
- sore throat
- fever

## This medicine treats:

- Fever
- Headache
- Minor body aches and pains
- Sore throat
- Stuffy nose
- Nasal and sinus congestion

- Keisha stayed home from school today because she is sick.
- She has a stuffy nose, sore throat, and aches all over.
- Mom gives her some Get Better cold and fever medicine before leaving for work.
- Two hours later, Keisha gets one of her really bad headaches.

## Keisha



- Keisha wants to take her usual headache medicine to make the headache go away.
- She calls mom at work.
- Mom asks Keisha to get both medicines and look at the labels.
- Mom asks Keisha about the active ingredients in her medicines.

## Keisha



## Grape Flavor

## Get Better **Cold and Fever** Suspension

Relieves:

Fever Stuffy Nose Minor aches and pains

Acetaminophen ► Pain reliever/ Fever reducer

Phenylephrine HCL▶ Nasal decongestant

## Drug Facts

### Active ingredients

Purposes

(in each 5 mL teaspoonful) Acetaminophen 500 mg ......Pain reliever/

fever reducer

Phenylephrine HCl 5 mg......Nasal decongestant

#### **Uses** temporarily relieves

- nasal and sinus congestion
   stuffy nose
- headache = sore throat
- minor aches and pains fever



## Drug Facts

#### Active ingredients

Purposes

(in each capsule)

Acetaminophen 500 mg ..... .Pain reliever/ fever reducer

#### Uses temporarily relieves

- headache
- sore throat
- minor aches and pains
   fever

Can Keisha take these medicines together? 15

## Grape Flavor

# Get Better Cold and Fever Suspension

Relieves:

Fever Stuffy Nose Minor aches and pains

Acetaminophen ► Pain reliever/
Fever reducer

Phenylephrine HCL►
Nasal decongestant

### Drug Facts

Active ingredients

Purposes

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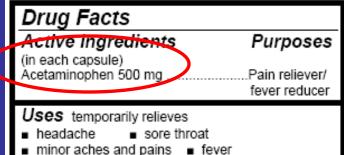
.Pain reliever/ fever reducer

Phenylephrine HCl 5 mg......Nasal decongestant

Uses temporarily relieves

- nasal and sinus congestion
   stuffy nose
- headache sore throat
- minor aches and pains
   fever





Both medicines contain the same active ingredient - acetaminophen.



Keisha can not take them together. 16



#### **Drug Facts**

#### Active ingredients

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- high blood pressure
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#### Ask a doctor or pharmacist before use if the child is

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- under a doctor's care for any continuing medical condition
- taking any other drug

#### Drug Facts (centinued)

#### When using this product

- take with food or milk if stomach upset occurs
- long term continuous use may increase the risk of heart attack or stroke

#### Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- the child does not get any relief during the first day (24 hours) of treatment
- fever, pain, or nasal congestion gets worse or lasts for more than 3 days
- stomach pain or upset gets worse or lasts
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- redness or swelling is present in the painful area
- the child gets nervous, dizzy, or sleepless
- any new symptoms appear

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#### Directions

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If possible use use age.

eat dose every 6 hours se more than 4 times a day

race original bottle cap to maintain child resistance

wash dosage cup after each use
 Dosing Chart

Maintain Management				
Weight (lb)	Age (yrs)	Dose		
		(teaspoonful)		
under 24	under 2	ask a doctor		
24-47	2 to 5	1 tsp		
48-95	6 to 11	2 tsp		

#### Other information

- do not use if printed neckband is broken or missing
- store at 15-30°C (59-86°F)
- see bottom of box for lot number and expiration date

Inactive ingredients acesulfame potassium, citric acid, com syrup, D&C red #33, FDA&C blue #1, FD&C red #40, flavors, glycerin, hypromellose, polysorbate 80, purified water, sodium benzoate, xanthan gum

Questions? 1-800-123-4567

http://ChildrensFeelBetter.com

# Warnings



## The warnings section tells you:

- When you should not use the medicine at all
- When you should talk to your doctor first
- How the medicine might make you feel
- When you should stop using the medicine
- Things you should not do while taking the medicine.





# Allergy Alert

When your body has an allergic reaction, you may have

- Itching

- Swelling

- Rash

- Fainting

- Hives

- Trouble breathing

- If you think you are allergic to a medicine, do not use it.
- If you think that you or someone else is having an allergic reaction,
  - tell an adult right away.
  - Call 911 for trouble breathing or fainting.

# Ask a doctor before use... Ask a doctor or pharmacist before use...



- When to ask a doctor, nurse, or pharmacist BEFORE using the medicine.
  - Some medical problems can make using a medicine less safe.
  - Some medicines should never be used together.



# When using this product...



- Special information about using the medicine.
- Examples...
  - Do not use more than directed
  - Take with food or milk if stomach upset occurs
  - Drowsiness may occur
  - Avoid contact with eyes.

# Stop use and ask a doctor if...

Reasons to stop taking a medicine include:



- If you have an allergic reaction
- If you have new problems like stomach pain, throwing up, or dizziness
- If you are not feeling better after a certain number of days

# Keep out of reach of children



- Young children may think medicine tastes REALLY GOOD.
- Medicine is not candy and can harm them if they take too much.
- If someone you know takes too much medicine or the wrong medicine, tell an adult right away. Call the Poison Control Center for help.

# Anthony

- 12 years old.
- Soccer goalie.
- Championship game today.
- Anthony has allergies: stuffy, runny nose and sneezing; watery eyes.
- What can he do?

Anthony speaks with his parents. Together, they look at the 2 allergy medicines in their home.



## Chewable Tablets

Grape Flavor

# Feel Better- Allergy Relief for kids and their grown-ups

Relieves: Sneezing, Runny nose Itchy, watery eyes

Chlorpheniramine ► Antihistamine



Because allergies should not get in the way

4 FI Oz (120 mL)



#### Chewable Tablets

Grape Flavor

## Feel Better- Allergy Relief for kids and their grown-ups

Relieves: Sneezing. Runny nose Itchy, watery eyes

Chlorpheniramine ► **Antihistamine** 



Because allergies should not get in the way

4 FI Oz (120 mL)



Under warnings, the label says:

"When using this product, you may get drowsy"

This is not the best choice before the championship game.

## Tony's mom reads the Drug Facts label:

The ingredient that treats allergy symptoms is chlorpheniramine

## **Drug Facts**

#### Active ingredient (in each tablet)

Purpose

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat

#### Warnings

Ask a doctor before use if you have

- glaucoma a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

#### When using this product

- You may get drowsy
- avoid alcoholic drinks
- lephol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

#### **Directions**

adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours	
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours	
children under 6 years	ask a doctor	

Other information store at 20-25° C (68-77° F) protect from excessive moisture

Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch



- Mom and dad look at the second allergy medicine.
- It has the same "Feel Better" name
- But the ingredient that treats allergy symptoms is different: loratadine.
- This medicine also has an ingredient to treat nasal congestion (stuffy nose)
- They all read the Drug Facts label

## Feel Better: Allergy and Congestion Relief

## Drug Facts

#### 

#### Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies;
- sneezing
- itchy, watery eyes
- runny nose
- itching of the nose or throat
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- reduces swelling of nasal passages
- temporarily relieves sinus congestion and pressure
- temporarily restores freer breathing through the nose

### Warnings

#### Do not use

- If you have ever had an allergic reaction to this product or any of its ingredients
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

#### Ask a doctor before use if you have

- heart disease
- thyroid disease
- high blood pressurediabetes
- . trouble urinating due to an enlarged prostate gland
- liver or kidney disease. Your doctor should determine if you need a different dose.

### Drug Facto

Taking more than directed may cause drowsiness.

- sympte
- nervousness, ute....

If pregnant or breast-feeding, ask a health professional before use.

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#### Directions

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adults and children 12 years and over than 2 tablets in 24 hours
children under 12 years of age consumers with liver or kidney disease

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 ask a doctor
ask a doctor

#### Other information

- safety sealed: do not use if the individual blister unit imprinted with Claritin-D<sup>®</sup> 12 Hr. is open or torn
- store between 15° to 25° C (59° to 77° F)
- keep in a dry place

#### Inactive ingredients

acacia, butyl paraben, calcium sulfate, carnauba wax, corn starch, lactose, magnesium stearate, microcrystalline cellulose, neutral soap, oleic acid, pharmaceutical ink, povidone, rosin, sugar, talc, titanium dioxide, white wax, zein

#### Questions or comments?

Under warnings, the label says:

int away.

red by a fever

"When using this product, taking more than directed may cause drowsiness"

Tony should never take more medicine than directed on the label.

With his parents permission, Tony takes the correct dose.

He soon feels better.

# Once you think you have found the right medicine for your problem...

What else do you need to know before you use your medicine?

#### Drug Facts

#### Active ingredients

#### Purposes

(in each 5 ml teaspoonful) Ibuprofen 100 mg (NSAID)\*.

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#### Drug Facts (continued)

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# How to use the medicine



## Directions



- How much medicine to use
- How often to use it
- How long you can use it

How should you measure your dose of medicine?

# Measuring Tools for Medicines



- Use the measuring spoon, cup, or syringe that comes with your medicine. This is the most exact way to measure your dose.
- If your medicine doesn't come with a special measuring tool, ask for one at the pharmacy.
- A silverware spoon may hold the wrong amount of medicine.
- Make sure the tool can measure the right dose check the markings on the tool.

# Other information and Inactive ingredients



- Other information tells you
  - How to keep your medicine when you are not using it.
- Inactive ingredients are used to:
  - Form a pill
  - Add flavor or color
  - Make a tablet or film dissolve quickly on your tongue
  - Help a medicine last longer on the shelf





## Questions or Comments

Where to find a telephone number or website to:

- ask questions about the medicine
- report an unexpected reaction to the medicine





## Questions or Comments

- If you have an unexpected reaction to a medicine, it is very important to call and let the company know.
- The companies that make medicines have to keep track of all unexpected reactions to their medicines.
   They must report serious reactions to the Food and Drug Administration within 15 days.
- The doctors and other scientists at the FDA look at these reports and watch for signs that a medicine may not be as safe as they thought.

## Be Safe!!



Use your OTC medicines wisely

# Take Home Messages

- Speak with a parent or adult before using any medicine.
- Read the label carefully.
  - The information you need to use your OTC medicine safely and correctly is in the Drug Facts Label.
- OTC medicines are serious medicines.
  - Be smart about what you put into your body it's the only body you have.



We hope you will share this information with your family.

Thank you.

