

# Pivotal Label Comprehension Study Mevacor™ OTC

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Capt. Laura Shay, RN, MS, C-ANP  
Division of Over-the-Counter Drug Products



Center for Drug Evaluation and Research

# Overview

- Purpose of a label comprehension (LC) study
- Mevacor™ OTC LC study design
- Summary of the study results

# Purpose of a Label Comprehension Study

- To evaluate whether or not consumers can comprehend important communication objectives on the label
  - Literate and low literate populations
  - Diverse population: Representative of the U.S. population

# Purpose of a Label Comprehension Study (cont.)

- Generally performed prior to the behavioral (actual use) study
- Low comprehension may be predictive of poor results in the actual use setting
- High comprehension does not necessarily guarantee success in the actual use setting

# Primary Objective Of the Mevacor OTC LC study

To evaluate consumer comprehension of the label used in the CUSTOM actual use study

# Secondary Objectives

- Determine how well respondents correctly respond to questions designed to try to measure self-selection
- Evaluate low literacy respondents
- Evaluate non-Caucasian respondents

# Key Communication Objectives

- Provided in your FDA background package  
(Tab 6, page 1)
- Summary of Results

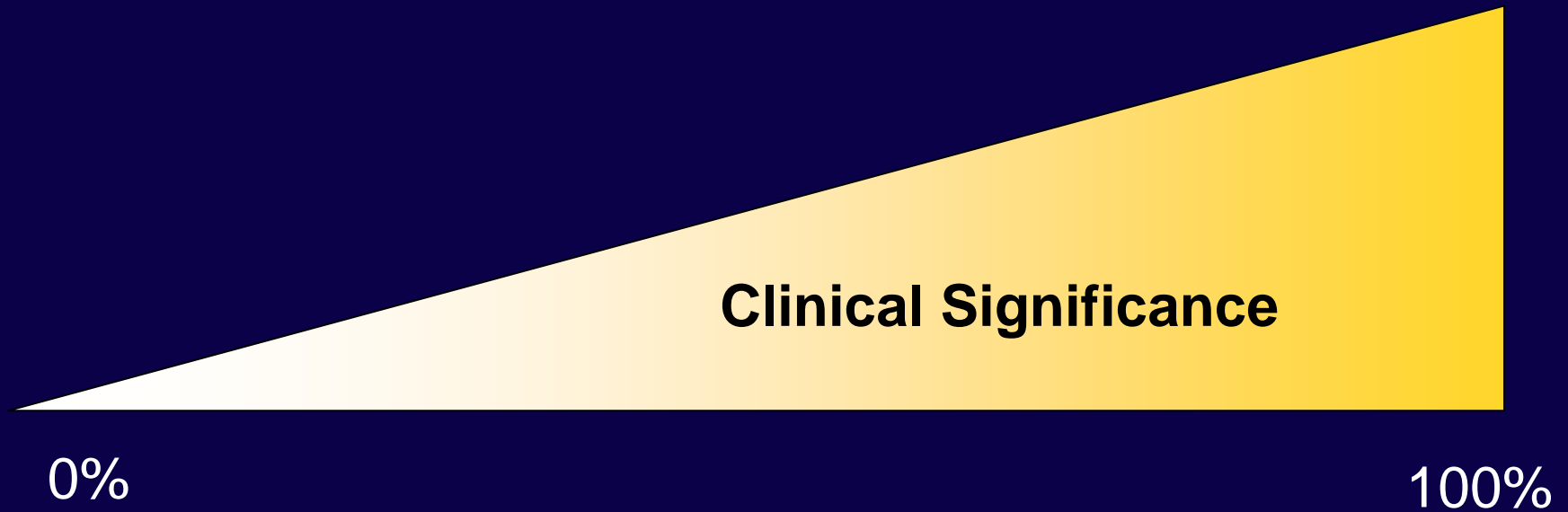
# 21 CFR 330.10 (a)(4)(v)

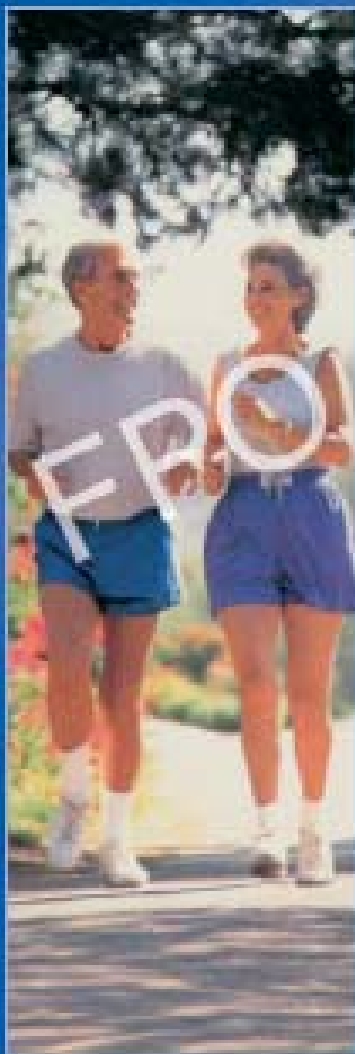
OTC labels must:

- . . .be likely to be read and understood by the ordinary individual, including individuals of low comprehension, under customary conditions of purchase and use.



# Assessment of Comprehension





Once-a-day  
**MEVACOR™**  
Lovastatin 20 mg  
CHOLESTEROL REDUCER **OTC**

- For people with elevated LDL "bad" cholesterol between 130-170 mg/dL
- To reduce LDL cholesterol to 129 or below and keep it down



Read back for  
more information

# Drug Facts

## Active ingredient (in each tablet)

Lovastatin 20 mg

## Purpose

Cholesterol reducer

**Use** To help lower LDL "bad" cholesterol, which may prevent a first heart attack. This product is for people who meet the requirements in the sections below.

## Warnings

### Do not use if

- **Liver disease:** Do NOT use if you have liver disease.
- Do NOT use if you have had any muscle pain, weakness or tenderness from taking a cholesterol-lowering medicine.
- **Pregnant or breast-feeding:** Do NOT use if you are pregnant or breast-feeding.
- **Allergic to lovastatin:** Do NOT use if you know you are allergic to lovastatin or the inactive ingredients in this medicine, as listed below.

### Ask your doctor or pharmacist before use if you are taking

- **Any prescription medicine:** If you are taking **any prescription medicine**, ask your doctor or pharmacist before taking MEVACOR™ OTC. Certain drugs can interact with MEVACOR™ OTC and can increase the possibility of side effects.
- **Other cholesterol-lowering medicine:** Do NOT substitute MEVACOR™ OTC for your **prescription or non-prescription cholesterol-lowering medicine** without talking to your doctor.
- **New prescriptions:** Tell your doctor or pharmacist you are taking MEVACOR™ OTC before you begin taking **any new prescription medicine**.

### Do NOT use unless directed by your doctor if you have

- very high LDL "bad" cholesterol 171-400 mg/dL
- high triglycerides 200-900 mg/dL
- healthy HDL "good" cholesterol 60-200 mg/dL
- had a stroke
- ever had heart disease (heart attack or angina)
- diabetes

Stop use and ask your doctor if you develop **any unexplained muscle pain**, weakness or tenderness. Stop use immediately. This can be a sign of a rare but serious side effect.

If you are diagnosed with a new medical condition, tell your doctor you are taking MEVACOR™ OTC.

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

## How to decide if MEVACOR™ OTC is right for you

### Before using you must have

- Tried a healthy diet and exercise to reduce your cholesterol.
- Had a fasting cholesterol test within the last year. If you do not know your numbers, call your doctor to get them or get a new test.

**Who can use:** You must have **YES (blue)** answers to all 4 of the following. Total cholesterol is important, but you must know your exact fasting LDL and HDL numbers.

- 1** MEVACOR™ OTC is only for men 45 years or older **AND** women 55 years or older

Yes, I am a man 45 or older or a woman 55 or older – continue ▶

Men 44 or younger or women 54 or younger

**STOP** Do not use - ask your doctor or pharmacist.

- 2** MEVACOR™ OTC is only for people with LDL "bad" cholesterol between 130 – 170 mg/dL

Yes, my LDL before use is 130 - 170 mg/dL – continue ▶

Between 1-129 mg/dL or 171-400 mg/dL or don't know

**STOP** Do not use - ask your doctor or pharmacist.

- 3** MEVACOR™ OTC is only for people with one or more of these conditions that increase heart risk: (If yes to any, you may need MEVACOR™ OTC.)

- ▶ You are a smoker (may need MEVACOR™ OTC) **OR**
- ▶ HDL "good" cholesterol 1-39 mg/dL (too low) **OR**
- ▶ Heart attack or angina in father or brother before 55; mother or sister before 65 **OR**
- ▶ High blood pressure

Yes, I have one or more of the above – continue ▶

I have none of the above or I'm not sure/don't know

**STOP** Do not use - ask your doctor or pharmacist.

- 4** MEVACOR™ OTC is only for people who are free of ALL conditions in the Warnings section above

Yes, I am free of all Warnings above – continue ▶

I have a condition listed in Warnings section or don't know

**STOP** Do not use - ask your doctor or pharmacist.

I have all YES (blue) answers. I can use MEVACOR™ OTC see directions below.

I have a **STOP** answer I cannot use.

## Directions

- 1** Take one tablet daily:

- If you stop taking MEVACOR™ OTC, your cholesterol will go back up.
- For best results, take it with the evening meal. (Your body makes more cholesterol at night.)
- Continue to eat a healthy diet and exercise.
- Do not take more than one tablet per day.

- 2** **Test at 6 weeks:** See if your LDL test result is 1-129 mg/dL: "YES" or "NO"?

- **NO** – If at 6 weeks your LDL "bad" cholesterol is higher than 129 mg/dL, **STOP** stop taking MEVACOR™ OTC. Talk to your doctor. MEVACOR™ OTC may not be enough for you.
- **YES** – If at 6 weeks your LDL "bad" cholesterol is 1-129 mg/dL, it's working, keep taking it daily and test your cholesterol once a year. If you stop, your cholesterol will go back up.
- For information on cholesterol testing, talk to your pharmacist or doctor.

- 3** Talk to your doctor if there is a change in your health:

- **New prescriptions:** Tell your doctor you are taking MEVACOR™ OTC before you begin taking **any** new prescription medicine.
- **New medical condition:** If diagnosed with a new medical condition, tell your doctor you are taking MEVACOR™ OTC.
- **Unexplained muscle pain:** Stop use immediately and talk to your doctor if you develop any unexplained muscle pain, weakness or tenderness. This can be a sign of a rare but serious side effect. ▼

## Drug Facts (continued)

**Inactive ingredients** Butylated hydroxyanisole (BHA), cellulose, FD&C blue No. 2 aluminum lake, lactose, magnesium stearate, and starch.

**Other information** See inside package for additional information or call toll free 1-800-XXX-XXXX or visit us on the web at www.xxxxxx.com

# Study Design

# Recruitment

Subjects were selected if they were found to be “cholesterol-concerned respondents”

Introducing New Non- Prescription Mevacor™ OTC

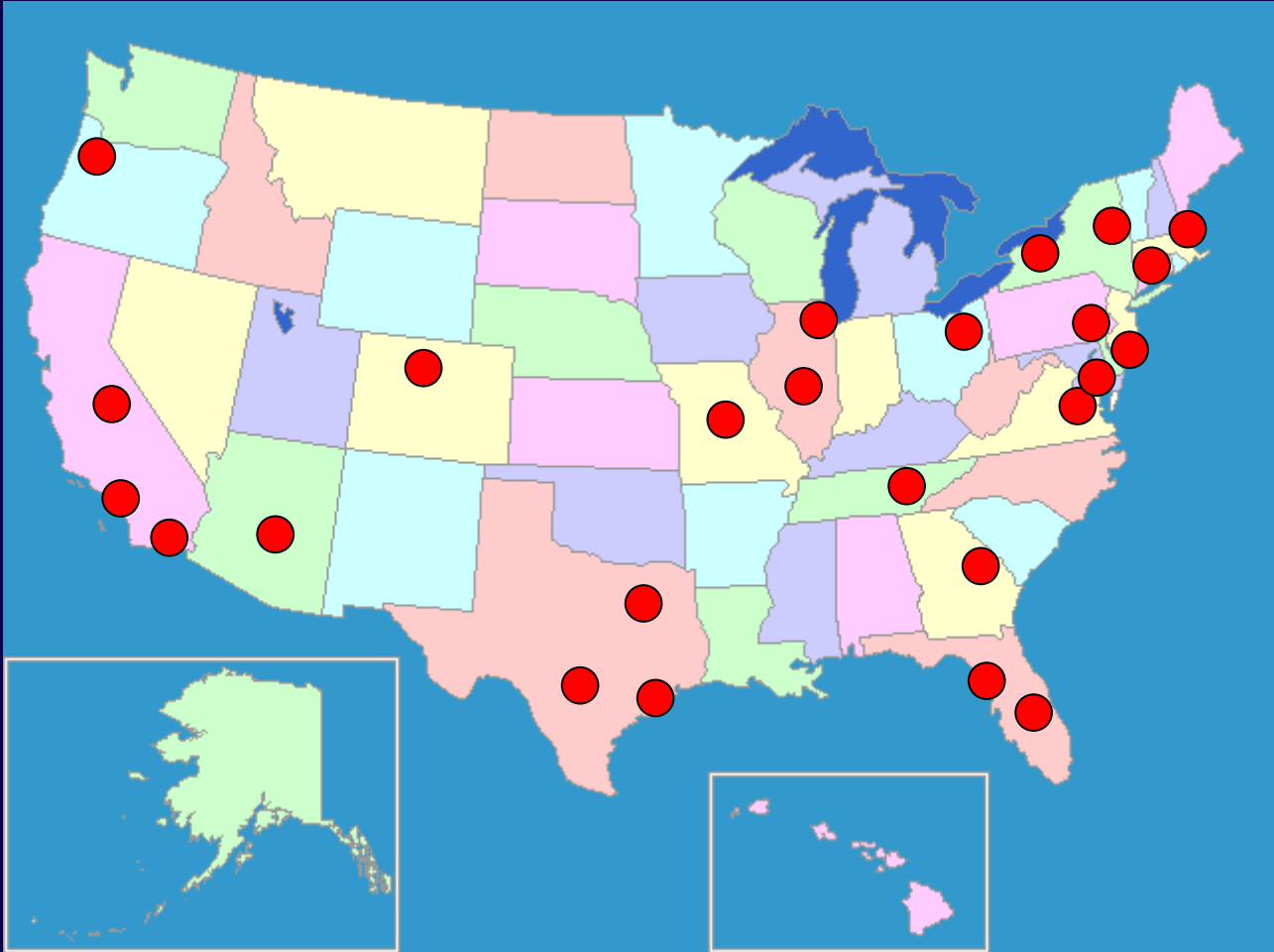


The advertisement features a black and white photograph of a man and a woman walking together outdoors. To the right of the photo is a dark box containing the text: **MEVACOR**<sup>®</sup>, Lovastatin 20 mg, CHOLESTEROL REDUCER, **OTC**, and *Lower Your Cholesterol*.

**The Simple Way to Lower Your Cholesterol!**

**Paid \$20-25 for participating**

# 25 sites (shopping malls) across the country



# Study Cohorts

- 696 Total representative sample
  - 203 Total low-literacy sample  
( $\leq 8^{\text{th}}$  grade reading level)
  - 493 Non low-literate sample
  - 207 Non-Caucasian sample
  - 489 Caucasian sample

# Gender

- 44% male
  - 51%  $\geq$  age 45
- 56% female
  - 35%  $\geq$  age 55



# Questionnaire

- Tested one label
- Structured interviews
- Refer to the label throughout the study
- Primarily multiple choice
- Scenarios were used to:
  - test key communication objectives
  - test decision making ability based on information found on the label

# Scenario for Unexplained Muscle Pain

Diane has been taking MEVACOR™OTC for several weeks. She didn't do any unusual physical activity and isn't feeling sick but she has started to feel pain in her leg muscles

# Drug Facts

Active ingredient (in each tablet)

Lovastatin 20 mg

Purpose

Cholesterol reducer

**Use** To help lower LDL "bad" cholesterol, which may prevent a first heart attack. This product is for people who meet the requirements in the sections below.

## Warnings

Do not use if

- **Liver disease:** Do NOT use if you have liver disease.
- Do NOT use if you have had any muscle pain, weakness or tenderness from taking a cholesterol-lowering medicine.
- **Pregnant or breast-feeding:** Do NOT use if you are pregnant or breast-feeding.
- **Allergic to lovastatin:** Do NOT use if you know you are allergic to lovastatin or the inactive ingredients in this medicine, as listed below.

Ask your doctor or pharmacist before use if you are taking

- **Any prescription medicine:** If you are taking **any prescription medicine**, ask your doctor or pharmacist before taking MEVACOR™ OTC. Certain drugs can interact with MEVACOR™ OTC and can increase the possibility of side effects.
- **Other cholesterol-lowering medicine:** Do NOT substitute MEVACOR™ OTC for your **prescription or non-prescription cholesterol-lowering medicine** without talking to your doctor.
- **New prescriptions:** Tell your doctor or pharmacist you are taking MEVACOR™ OTC before you begin taking **any new prescription medicine**.

**Stop use and ask your doctor if you develop any unexplained muscle pain, weakness or tenderness. Stop use immediately. This can be a sign of a rare but serious side effect.**

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

## How to decide if MEVACOR™ OTC is right for you

Before using you must have

- Tried a healthy diet and exercise to reduce your cholesterol.
- Had a fasting cholesterol test within the last year. If you do not know your numbers, call your doctor to get them or get a new test.

**Who can use:** You must have **YES (blue)** answers to all 4 of the following. Total cholesterol is important, but you must know your exact fasting LDL and HDL numbers.

- 1 MEVACOR™ OTC is only for men 45 years or older **AND** women 55 years or older

Yes, I am a man 45 or older or a woman 55 or older – continue ▶

Men 44 or younger or women 54 or younger  
**STOP** Do not use - ask your doctor or pharmacist.

- 2 MEVACOR™ OTC is only for people with LDL "bad" cholesterol between 130 - 170 mg/dL

Yes, my LDL before use is 130 - 170 mg/dL – continue ▶

Between 1-129 mg/dL or 171-400 mg/dL or don't know  
**STOP** Do not use - ask your doctor or pharmacist.

- 3 MEVACOR™ OTC is only for people with one or more of these conditions that increase heart risk: (if yes to any, you may need MEVACOR™ OTC.)

- ▶ You are a smoker (may need MEVACOR™ OTC) **OR**
- ▶ HDL "good" cholesterol 1-39 mg/dL (too low) **OR**
- ▶ Heart attack or angina in father or brother before 55; mother or sister before 65 **OR**
- ▶ High blood pressure

Yes, I have one or more of the above – continue ▶

I have none of the above or I'm not sure/don't know  
**STOP** Do not use - ask your doctor or pharmacist.

- 4 MEVACOR™ OTC is only for people who are free of ALL conditions in the Warnings section above

Yes, I am free of all Warnings above – continue ▶

I have a condition listed in Warnings section or don't know  
**STOP** Do not use - ask your doctor or pharmacist.

I have all YES (blue) answers. I can use MEVACOR™ OTC see directions below.

I have a **STOP** answer I cannot use.

## Directions

- 1 Take one tablet daily:

- If you stop taking MEVACOR™ OTC, your cholesterol will go back up.
- For best results, take it with the evening meal. (Your body makes more cholesterol at night.)
- Continue to eat a healthy diet and exercise.
- Do not take more than one tablet per day.

- 2 Test at 6 weeks: See if your LDL test result is 1-129 mg/dL: "YES" or "NO"?

- **NO** – If at 6 weeks your LDL "bad" cholesterol is higher than 129 mg/dL, **STOP** stop taking MEVACOR™ OTC. Talk to your doctor. Your cholesterol may not be enough for you.
- **YES** – If at 6 weeks your LDL "bad" cholesterol is 1-129 mg/dL, continue taking it daily and test your cholesterol once a year.
- For information on cholesterol testing, talk to your doctor.

- 3 Talk to your doctor if there is a change in your health:

- **New prescriptions:** Tell your doctor you are taking MEVACOR™ OTC.

**Unexplained muscle pain: Stop use immediately** and talk to your doctor if you develop any unexplained muscle pain, weakness or tenderness. This can be a sign of a rare but serious side effect.

Drug Facts (continued)

**Inactive ingredients** Butylated hydroxyanisole (BHA), cellulose, FD&C blue No. 2 aluminum lake, lactose, magnesium stearate, and starch.

**Other information** See inside package for additional information or call toll free 1-800-XXX-XXXX or visit us on the web at www.xxxxxxx.com

# Answer Definitions

- Correct:  
If a respondent's answer adhered to the label
- Acceptable:  
If a respondent's answer did not specifically adhere to the label  
“but would not pose a safety risk”

# Answer Options for the Unexplained Muscle Pain Scenario

- Stop using Mevacor OTC. Must talk to a doctor **(C)**
- Continue to use Mevacor OTC but must talk to a doctor **(A)**
- Stop using Mevacor OTC. Does not need to talk to doctor **(A)**
- Continue to use Mevacor OTC and does not need to talk to a doctor **(I)**
- Don't know **(I)**

# Results of the Unexplained Muscle Pain Scenario:

<i>Cohorts</i>	<i>Correct</i>	<i>Correct plus Acceptable</i>
Total	<b>79%</b>	<b>98%</b>
Caucasian	<b>81%</b>	<b>98%</b>
Non-Caucasian	<b>74%</b>	<b>99%</b>
Non-Low Literacy	<b>79%</b>	<b>99%</b>
Low Literacy	<b>79%</b>	<b>97%</b>

# Scenario for Liver Disease

Barbara has liver disease:



# Drug Facts

## Active ingredient (in each tablet)

Lovastatin 20 mg

## Purpose

Cholesterol reducer

**Use** To help lower LDL "bad" cholesterol, which may prevent a first heart attack. This product is for people who meet the requirements in the sections below.

### Warnings

## Liver disease: Do NOT use if you have liver disease.

- **Pregnant or breast-feeding:** Do NOT use if you are pregnant or breast-feeding.
- **Allergic to lovastatin:** Do NOT use if you know you are allergic to lovastatin or the inactive ingredients in this medicine, as listed below.

### Ask your doctor or pharmacist before use if you are taking

- **Any prescription medicine:** If you are taking **any prescription medicine**, ask your doctor or pharmacist before taking MEVACOR™ OTC. Certain drugs can interact with MEVACOR™ OTC and can increase the possibility of side effects.
- **Other cholesterol-lowering medicine:** Do NOT substitute MEVACOR™ OTC for your **prescription or non-prescription cholesterol-lowering medicine** without talking to your doctor.
- **New prescriptions:** Tell your doctor or pharmacist you are taking MEVACOR™ OTC before you begin taking **any new prescription medicine**.

### Do NOT use unless directed by your doctor if you have

- very high LDL "bad" cholesterol 171-400 mg/dL
- high triglycerides 200-900 mg/dL
- healthy HDL "good" cholesterol 60-200 mg/dL
- had a stroke
- ever had heart disease (heart attack or angina)
- diabetes

Stop use and ask your doctor if you develop **any unexplained muscle pain**, weakness or tenderness. Stop use immediately. This can be a sign of a rare but serious side effect.

If you are diagnosed with a new medical condition, tell your doctor you are taking MEVACOR™ OTC.

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

## How to decide if MEVACOR™ OTC is right for you

Before using you must have

- Tried a healthy diet and exercise to reduce your cholesterol.
- Had a fasting cholesterol test within the last year. If you do not know your numbers, call your doctor to get them or get a new test.

**Who can use:** You must have YES (blue) answers to all 4 of the following. Total cholesterol is important, but you must know your exact fasting LDL and HDL numbers.

- 1** MEVACOR™ OTC is only for men 45 years or older AND women 55 years or older

Yes, I am a man 45 or older or a woman 55 or older – continue ▶

Men 44 or younger or women 54 or younger

**STOP** Do not use - ask your doctor or pharmacist.

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Yes, my LDL before use is 130 - 170 mg/dL – continue ▶

Between 1-129 mg/dL or 171-400 mg/dL or don't know

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- ▶ HDL "good" cholesterol 1-39 mg/dL (too low) **OR**
- ▶ Heart attack or angina in father or brother before 65; mother or sister before 65 **OR**
- ▶ High blood pressure

Yes, I have one or more of the above – continue ▶

I have none of the above or I'm not sure/don't know

**STOP** Do not use - ask your doctor or pharmacist.

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Yes, I am free of all Warnings above – continue ▶

I have a condition listed in Warnings section or don't know

**STOP** Do not use - ask your doctor or pharmacist.

I have all YES (blue) answers. I can use MEVACOR™ OTC see directions below.

I have a STOP answer I cannot use.

## Directions

- 1** Take one tablet daily:

- If you stop taking MEVACOR™ OTC, your cholesterol will go back up.
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- Continue to eat a healthy diet and exercise.
- Do not take more than one tablet per day.

- 2** **Test at 6 weeks:** See if your LDL test result is 1-129 mg/dL: "YES" or "NO"?

- **NO** – If at 6 weeks your LDL "bad" cholesterol is higher than 129 mg/dL, **STOP** stop taking MEVACOR™ OTC. Talk to your doctor. MEVACOR™ OTC may not be enough for you.
- **YES** – If at 6 weeks your LDL "bad" cholesterol is 1-129 mg/dL, it's working, keep taking it daily and test your cholesterol once a year. If you stop, your cholesterol will go back up.
- For information on cholesterol testing, talk to your pharmacist or doctor.

- 3** Talk to your doctor if there is a change in your health:

- **New prescriptions:** Tell your doctor you are taking MEVACOR™ OTC before you begin taking **any** new prescription medicine.
- **New medical condition:** If diagnosed with a new medical condition, tell your doctor you are taking MEVACOR™ OTC.
- **Unexplained muscle pain:** Stop use immediately and talk to your doctor if you develop any unexplained muscle pain, weakness or tenderness. This can be a sign of a rare but serious side effect. ▼

## Drug Facts (continued)

**Inactive ingredients** Butylated hydroxyanisole (BHA), cellulose, FD&C blue No. 2 aluminum lake, lactose, magnesium stearate, and starch.

**Other information** See inside package for additional information or call toll free 1-800-XXX-XXXX or visit us on the web at www.xxxxxx.com



# Answer Options for the Liver Disease Scenario

- This person should not use at all **(C)**
- Before using, this person needs to talk to a doctor **(A)**
- This person could start using right away **(I)**
- Don't know **(I)**

# Results of the Liver Disease Scenario:

<i>Cohorts</i>	<i>Correct</i>	<i>Correct plus Acceptable</i>
Total	<b>69 %</b>	<b>99 %</b>
Caucasian	<b>68 %</b>	<b>99 %</b>
Non-Caucasian	<b>71 %</b>	<b>99 %</b>
Non-Low Literacy	<b>70 %</b>	<b>99 %</b>
Low Literacy	<b>65 %</b>	<b>100 %</b>

# Study Results

Based on % of Correct Answers from the Total Representative Sample

(answers adhered to the label)



## % Correct Answers: Dosing, Other Info:

- 99% What the product is used for
- 99% Dosage and dosing information
- 95% Need to consult with health care professional prior to use if on a Rx drug
- 92% Active ingredient
- 87% Time frame for cholesterol testing
- 86% Prerequisite of diet and exercise before taking the medication
- 82% Evening best time of day for dosing
- 78% Need to fast for cholesterol testing
- 59% Cholesterol will go up if Mevacor™ OTC is stopped

# **% Correct Answers for Scenarios that Indicate the Need to Stop Mevacor™ OTC:**

- **47%-90%**
- **79%** Unexplained muscle pain

# % Correct Answers: Self-selection Scenarios

- 37-81%
  - 54%: average correct answers
  - 72%: allergy to lovastatin
  - 42%: prior Hx of muscle pain on a cholesterol-lowering medicine

# % Correct Answers: Listed Under the “Do Not Use If”

- 74% pregnant
- 77% breast feeding
- 69% liver disease

# % Correct Answers: False Positives

	<i>Correct</i>	<i>Correct plus Acceptable</i>
Developed a Cold	<b>66%</b>	<b>98%</b>
Tums for Indigestion	<b>72%</b>	<b>96%</b>
Poison Ivy	<b>64%</b>	<b>94%</b>
Gas from Food	<b>69%</b>	<b>95%</b>
Constipation	<b>64%</b>	<b>95%</b>



# Self-Selection

Respondents were asked if they could start Mevacor™ OTC today. This answer was compared to the self-reported medical history questions and demographic data in order to validate if the response was correct

# Self-selection

- 696 Total Representative Sample
  - 461 respondents reported they “could not start Mevacor OTC today”
  - 209 respondents reported they “could start Mevacor OTC today”
  - 26 respondents reported they “Did not know”

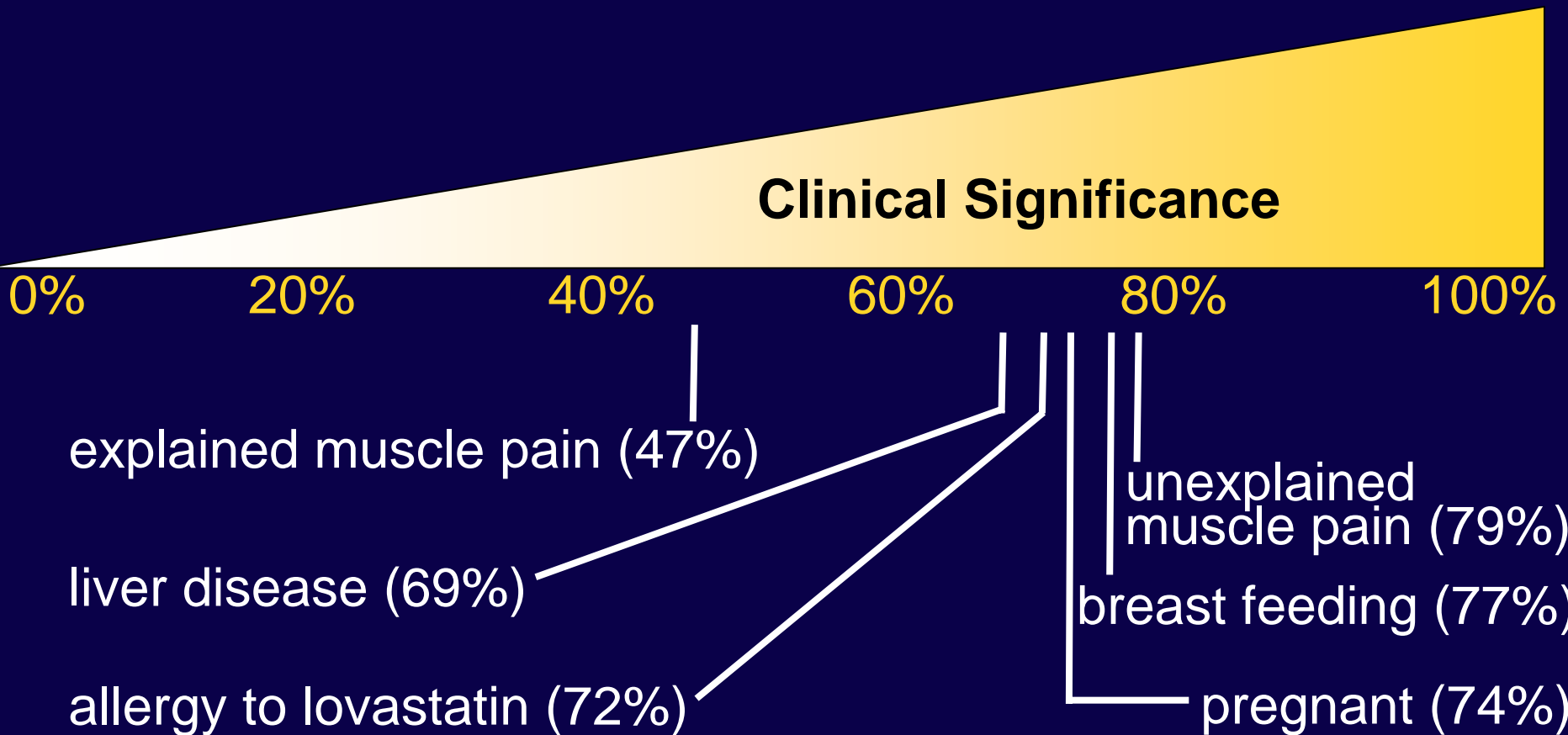
# Self-selection Results

- 461 (100%) out of the 461 Respondents who reported they “could not start Mevacor OTC today” self-selected correctly according to label criteria
- 3 (1%) out of the 209 Respondents who reported they “could start Mevacor OTC today” self-selected correctly according to label criteria
- 464 (67%) out of the 696 total Respondents self-selected correctly according to label criteria

# Summary: Study Design

- Well designed study
  - Diverse population
  - Non-Caucasian and low-literate
  - Non-leading well constructed Questions
  - Study was able to distinguish varied levels of comprehension

# Summary: Clinically Significant Communication Objectives



# Summary: Self-Selection

- Total number who self-selected correctly according to the label
  - 464 out of 696 **(67%)**
- “Could start Mevacor <sup>TM</sup> OTC today”
  - 3 out of 209 **(1%)**

# Summary: Correct vs. Acceptable

- “acceptable” answers increased most scores >90%
- Some “acceptable responses” could be correct:
  - Do Not Use-Ask a doctor or pharmacist or
  - Do Not Use unless directed by your doctor
- The “acceptable” answers often contained “ask a doctor” even when not indicated to do so on the label
- Respondents often had a  $\geq 50\%$  (3 out of 5) chance of selecting either a correct or “acceptable” answer