

Phase 1 High Cholesterol FDA Online Study Survey Instrument

SCREENING / INTRODUCTION

Thank you for agreeing to participate in this study today. Make sure you are comfortable and can read the screen from where you sit. The survey will include some audio, so please make sure the sound is on and the speaker volume is turned up.

This study will take about 25 minutes to complete. We ask you to please complete the study in one sitting (without taking any breaks) in order to avoid distractions.

This study is about a new medicine. The study has three parts: First, we will ask you a few health-related questions. Next, we will let you explore a Web site about the new medicine. Finally, we will ask you some questions about the medicine.

S1. [Illness Diagnosis #1]

Have you ever been diagnosed by a health professional with any of the following conditions?
(Check all that apply)

- Arthritis
- Sleep Apnea
- High Cholesterol → [Continue]
- Crohn's Disease
- Diabetes
- None of the above

S2. [Illness Diagnosis #2]

Do you still have high cholesterol?

- Yes → [Skip to Q-HC1]
- No → [Continue to S3]

S3. [Illness Diagnosis #3]

Have you taken any medication for high cholesterol in the past 12 months?

- Yes → [Continue]
- No → [Terminate]

The next few questions ask about high cholesterol. The purpose of these questions is to find out what most people know and understand about high cholesterol. Please answer the questions to the best of your ability. If you don't know the answer to a question, it is okay to check the box that says "Don't know".

Q-HC1. [High Cholesterol Knowledge #1]

What type of cholesterol is known as "bad cholesterol"?

- LDL (low density lipoprotein)
- HDL (high density lipoprotein)
- VLDL (very low density lipoprotein)
- Chylomicrons
- Don't know

Q-HC2. [High Cholesterol Knowledge #2]

What is one way to treat high cholesterol?

- Eat foods with fiber in them, like whole grains
- Get extra rest, such as 8-10 hours of sleep per night
- Take vitamin C supplement each morning
- Eat smaller portions at each meal
- Don't know

Q-HC4. [High Cholesterol Knowledge #4]

High cholesterol can lead to:

- Vertigo
- Rheumatoid arthritis
- Chronic lower back pain
- Stroke
- Don't know

Q-HC5. [High Cholesterol Knowledge #5]

Which of the following is a symptom of high cholesterol?

- Constipation
- Bloating
- Fatigue
- None - High cholesterol is usually detected by lab tests
- Don't know

WEB SITE INSTRUCTIONS

On the next screen, you will see a Web site for a new product. The Web site will open in a new window. Please read the information on the site. You can take as much time as you want to review it.

The Web site has 5 pages. Feel free to explore the site, click on any links, and read the information as if you wanted to learn more about the new product. Once you finish reading, please click *Next* to move to the next part of the study.

Please make sure you have the speakers on your computer turned up so you can hear any audio.

[DIRECT PARTICIPANTS TO APPROPRIATE WEB SITE]

SURVEY INSTRUCTIONS

Please answer the following questions based on the Web site you visited.

Q1. [Web Site Viewing]

Were you able to view and explore the Web site for PEXACOR?

Yes

No → [Terminate]

Q2. [Drug Knowledge (indication, illness)]

What condition does PEXACOR treat?

High Cholesterol

High Blood Pressure

Anemia (Low Red Blood Cells)

Congestive Heart Failure

Q3. [Embedded Visual Recall / Risk Info Exposure Proxy]

The Web site included a picture of the PEXACOR pill. What did that pill look like?

The pill was red and oval

The pill was purple and oval

The pill was blue and round

The pill was white and round

I did not see the pill

[PHASE 1: ASK Q8-11 BEFORE Q4-7]

Q8. [Risk Recall]

What are the side effects and negative outcomes of PEXACOR?

(open ended)

[DISPLAY Q9 AND Q10 ON THE SAME SCREEN]

When considering a new medicine, most people ask two questions:

- (1) Will this medicine cause any side effects?
- (2) If it does cause side effects, how serious will the side effects be?

The questions below ask about these two ideas.

Q9. [Perceived Risk - Likelihood of Risk]

In your opinion...if 100 people take PEXACOR, how many will have any side effects or negative outcomes? Please enter a number in the box below.

___ people

Q10. [Perceived Risk - Magnitude of Risk]

In your opinion...if PEXACOR did cause a person to have side effects or negative outcomes, how serious would they be?

1	2	3	4	5	6
Not at all serious					Very serious

Q11. [Risk Recall - Closed]

Please check which of the following were mentioned on the Web site as warnings, side effects, or negative outcomes of taking PEXACOR. Even if you think a statement is true, please select it only if it was mentioned on the site.

[RANDOMIZE ORDER]	Mentioned on Web Site	Not Mentioned on Web Site
a. PEXACOR cannot be taken by people who have liver problems.	x	
b. PEXACOR can cause thrombotic thrombocytopenic purpura (TTP).	x	
c. A side effect of PEXACOR is diarrhea.	x	
d. Patients taking PEXACOR may be at higher risk for internal bleeding.		x
e. PEXACOR can cause birth defects.	x	
f. A side effect of PEXACOR is difficulty concentrating.		x
g. Side effects of PEXACOR usually occur within one month of starting therapy.		x
h. People who are taking other cholesterol medications cannot take PEXACOR.		x

Q4. [Benefit Recall]

What are the benefits of PEXACOR?

(open ended)

[DISPLAY Q5 AND Q6 ON SAME SCREEN]

When considering a new medicine, most people ask two questions:

- (1) Will this medicine work?
- (2) If it does work, will it help a little or help a lot?

The questions below ask about these two ideas.

Q5. [Perceived Efficacy - Likelihood of Benefit]

In your opinion...If 100 people take PEXACOR, for how many will the drug work? Please enter a number in the box below.

___ people

Q6. [Perceived Efficacy - Magnitude of Benefit]

In your opinion...If PEXACOR did help a person’s high cholesterol, how effective would PEXACOR be?

1 2 3 4 5 6
Would help high cholesterol very little Would help high cholesterol a lot

Q7. [Benefit Recall - Closed] [Benefit Knowledge]

Please check which of the following were mentioned on the Web site as benefits of taking PEXACOR. Even if you think a statement is true, please select it only if it was mentioned on the site.

[RANDOMIZE ORDER]	Mentioned on Web Site	Not Mentioned on Web Site
a. PEXACOR can lower levels of LDL cholesterol (bad cholesterol).	x	
b. PEXACOR can lower levels of fats (triglycerides) in the blood.	x	
c. PEXACOR can raise levels of HDL cholesterol (good cholesterol).	x	
d. PEXACOR can raise the number of red blood cells (RBCs).		x
e. PEXACOR contains an enzyme that helps people lose weight.		x
f. PEXACOR has been proven to reverse heart disease.		x
g. PEXACOR is a type of statin.	x	
h. PEXACOR can lower blood pressure.		x

The next few questions ask about PEXACOR’s risk and benefits. By risks, we mean the drug’s possible side effects and negative outcomes. By benefits, we mean the drug’s ability to improve symptoms of high cholesterol.

Q12. [Drug Balance of Risks / Benefits]

Thinking about all its risks and benefits, how would you rate PEXACOR:

1 2 3 4 5 6 7
Risks outweigh benefits Benefits
outweigh risks

Q18. [Perceived Clarity / Understanding of Site]

Please rate your agreement or disagreement with each of the following statements.

[RANDOMIZE ORDER]	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
a. The Web site clearly communicated the <i>benefits</i> of PEXACOR.					
b. The Web site clearly communicated the <i>risks</i> of PEXACOR.					

Q13. [Web Site Balance of Risks / Benefits]

Please think about how the risks and benefits of PEXACOR were presented on the Web site. Did the site place more emphasis on risks or more emphasis on benefits?

1	2	3	4	5	6	7	
More emphasis on risks benefits					More emphasis on		

Q14. [Behavioral Intentions (seek drug info, talk to doc, etc.)]

Based on what you learned, please rate how likely or unlikely you are to do each of the following behaviors.

[RANDOMIZE ORDER]	Very Unlikely	Somewhat Unlikely	Neither Likely nor Unlikely	Somewhat Likely	Very Likely
a. Talk to your doctor about PEXACOR					
b. Ask your doctor about getting a sample of PEXACOR					
c. Ask your doctor to prescribe PEXACOR					
e. Join an online community or support group <i>for people with high cholesterol</i>					

f. Join an online community or support group <i>sponsored by PEXACOR</i>					
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Q15. [Behavioral Intentions (seek drug info, talk to doc, etc.)]

Based on what you learned, please rate how likely or unlikely you are to do each of the following behaviors.

[RANDOMIZE ORDER]	Very Unlikely	Somewhat Unlikely	Neither Likely nor Unlikely	Somewhat Likely	Very Likely
a. Look for information online about other people's experience with PEXACOR					
b. Look for information <i>about PEXACOR</i> on medical Web sites					
c. Look for information <i>about high cholesterol</i> on medical Web sites					
d. Print information from PEXACOR.com to discuss with your doctor					

Q16. [Attitudes Toward Drug]

Based on what you learned, please rate PEXACOR. [RANDOMIZE ORDER OF ROWS]

	1	2	3	4	5	6	7	
Bad product								Good product
Disliked a lot								Liked a lot
Unpleasant								Pleasant
Poor quality								Good quality

Q19. [Site Skepticism]

Strongly
Disagree

Strongly
Agree

Q25. [Trust in Online Information (HMTS)]

In general, how much do you or would you trust information about prescription drugs from each of the following sources?

[RANDOMIZE ORDER]	Not at all	A little	Some	A lot
Drug Web sites (example: Pexacor.com)				
Medical Web sites (example: WebMD.com)				
Online communities for people with high cholesterol (example: Healthboards.com)				
Family and friends				
Doctors, nurses, and healthcare providers				
Food and Drug Administration (FDA)				
Pharmaceutical companies				
Prescription drug advertisements				

Q26. [Current Prescription Drug Use]

Are you currently taking, or have you ever taken, any prescription drugs for high cholesterol?

- Currently taking
- Have taken in the past but not currently taking
- Have never taken

Q27. [History of Side Effects]

Have you ever had a **SERIOUS** side effect from a prescription drug?

- Yes
- No
- Don't Know

Q28. [Time Since Diagnosis]

When did a healthcare professional first tell you that you had high cholesterol?

- Six months ago or less
- More than six months ago but less than a year ago
- A year ago or more but less than 5 years
- Five years ago or longer

Q29. [Severity of Illness - Subjective]

In general, how severe is your high cholesterol? Would you describe it as:

- Very mild
- Mild
- Moderate
- Serious
- Severe

Q31. [Health Literacy - Assistance (Leaflet Study)]

How often do you have someone (like a family member or friend) help you read instructions, pamphlets, or other written material from your doctor or pharmacy?

- Never
- Occasionally
- Sometimes
- Often
- Always

Q32. [Health Literacy - Self Efficacy (Leaflet Study)]

How confident are you filling out medical forms by yourself?

- Not at all
- A little bit
- Somewhat
- Quite a bit
- Extremely

Q33. [Survey Device]

What did you use to complete today's survey?

- Laptop computer / Netbook computer
- Desktop computer
- Handheld phone (iPhone, Blackberry, Droid)
- Handheld device other than a phone (iPod Touch, Palm Pilot, iPad)
- Other: _____

CLOSING

The purpose of this study is to learn about how individuals use information from medical Web sites. In order to get a real-life reaction, we used a pretend product in this study.

PEXACOR is not a real product and is not available for sale. Please see your healthcare provider for questions about high cholesterol.

You have been very helpful. Thank you very much for your participation!