

Phase 2 High Blood Pressure 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 Blood Pressure → [Continue]
- Crohn's Disease
- Diabetes
- None of the above

S2. [Illness Diagnosis #2]

Do you still have high blood pressure?

Do you still have high blood pressure?

Yes → [Skip to Q-HBP1]

No → [Continue to S3]

S3. [Illness Diagnosis #3]

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

Yes → [Continue]

No → [Terminate]

The next few questions ask about high blood pressure. The purpose of these questions is to find out what most people know and understand about high blood pressure. 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-HBP1. [High Blood Pressure Knowledge #1]

Which of the following is another name for high blood pressure?

- Hypotension
- Hypertension
- Hyperlipidemia
- Hyperthyroidism
- Don't know

Q-HBP2. [High Blood Pressure Knowledge #2]

A normal blood pressure is:

- 120/80
- 80/120
- 200/60
- 60/200
- Don't know

Q-HBP3. [High Blood Pressure Knowledge #3]

Which of the following is a possible contributor to high blood pressure?

- Obesity
- Lack of sleep
- A high amount of fiber in the diet
- Young age
- Don't know

Q-HBP4. [High Blood Pressure Knowledge #4]

High blood pressure increases the risk of:

- Cancer
- Stroke
- Pneumonia
- Chronic lower back pain
- Don't know

Q-HBP5. [High Blood Pressure Knowledge #5]

Systolic blood pressure is:

- Measured while the heart is contracting (e.g., pumping blood into the arteries)
- Measured while the heart is relaxed (e.g., not pumping blood into the arteries)
- The second number in a blood pressure reading
- Expressed in millimeters of magnesium
- 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 PLISTAZ?

Yes

No → [Terminate]

Q2. [Drug Knowledge (indication, illness)]

What condition does PLISTAZ treat?

High Blood Pressure

High Cholesterol

Anemia (Low Red Blood Cells)

Congestive Heart Failure

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

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

The pill was red and oval

The pill was pink and round

The pill was white and round

The pill was gray and oval

I did not see the pill

Q4. [Benefit Recall]

What are the benefits of PLISTAZ?

(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 PLISTAZ, 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 PLISTAZ did help a person's blood pressure, how effective would PLISTAZ be?

1 2 3 4 5 6
Would help blood pressure very little Would help blood pressure a lot

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

Please check which of the following were mentioned on the Web site as benefits of taking PLISTAZ. 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. PLISTAZ is an anti-hypertensive medication.	x	
b. PLISTAZ lowers blood pressure by reducing the amount of renin in the body.	x	
c. PLISTAZ is taken only once a week.	x	
d. PLISTAZ helps the body to circulate blood more efficiently.		x
e. PLISTAZ must be used with other blood pressure medications to work correctly.		x
f. PLISTAZ contains an enzyme that helps people lose weight.		x
g. By lowering blood pressure, PLISTAZ can lower the risk of having a stroke or heart attack.	x	
h. PLISTAZ has been shown to lower blood pressure in as little as two weeks.		x

Q8. [Risk Recall]

What are the side effects and negative outcomes of PLISTAZ?

(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 PLISTAZ, 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 PLISTAZ 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 Very
 serious 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 PLISTAZ. 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. PLISTAZ can cause injury or death to an unborn baby.	x	
b. When taking PLISTAZ, people should not use salt.	x	
c. A common side effect of PLISTAZ is diarrhea.	x	
d. A common side effect of PLISTAZ is dizziness.		x
e. People who have had angioedema should talk to their doctor before taking PLISTAZ.	x	
f. People with kidney disease may need special tests when taking PLISTAZ.		x
g. In rare cases, PLISTAZ can cause liver damage.		x
h. When taking PLISTAZ, people should not drink beverages with caffeine.		x

Q-V1. [Awareness of Special Feature - Interactive Visual]

This Web site had a video that showed how PLISTAZ works.

True
 False

*****V2 TO V5 FOR ANIMATION ONLY*****

Q-V2. [Exposure to Special Feature - Interactive Visual]

[IF TRUE TO Q-V1] Did you watch this video about PLISTAZ?

- Yes
- No

Q-V3. [Perceived Visual Accuracy]

[IF TRUE TO Q-V1] How likely or unlikely is it that this video accurately shows how PLISTAZ works in real people?

- | | | | | | | |
|-----------------------|---|---|---|---|---|---------------------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Extremely
Unlikely | | | | | | Extremely
Likely |

Q-V4-A. [Visual Effect on Drug Benefit Perceptions]

[IF TRUE TO Q-V1] After watching the video, were you more confident or less confident that PLISTAZ will be effective?

- | | | | | |
|----------------|---|-----------|---|----------------|
| 1 | 2 | 3 | 4 | 5 |
| Less confident | | No change | | More confident |

Q-V4-B. [Visual Effect on Drug Risk Perceptions]

[IF TRUE TO Q-V1] After watching the video, were you more concerned or less concerned about PLISTAZ's side effects and negative outcomes?

- | | | | | |
|----------------|---|-----------|---|----------------|
| 1 | 2 | 3 | 4 | 5 |
| Less concerned | | No change | | More concerned |

Q-V5. [Reason for Not Watching Visual]

[IF NO TO Q-V2] Why didn't you watch this video about PLISTAZ?

(open ended)

*******END ANIMATION QUESTIONS*******

Q-T1. [Awareness of Special Feature - Testimonial]

This Web site had a video of a patient who has used PLISTAZ.

- True
- False

*******T2 TO T6 FOR TESTIMONIAL ONLY*******

The next few questions ask about PLISTAZ’s risks 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 blood pressure.

Q12. [Drug Balance of Risks / Benefits]

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

1 2 3 4 5 6 7

Risks outweigh benefits
outweigh risks

Benefits

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 PLISTAZ.					
b. The Web site clearly communicated the <i>risks</i> of PLISTAZ.					

Q13. [Web Site Balance of Risks / Benefits]

Please think about how the risks and benefits of PLISTAZ 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 PLISTAZ					
b. Ask your doctor about getting a sample of PLISTAZ					
c. Ask your doctor to prescribe PLISTAZ					
e. Join an online community or support group <i>for people with high blood pressure</i>					
f. Join an online community or support group <i>sponsored by PLISTAZ</i>					

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 PLISTAZ					
b. Look for information <i>about PLISTAZ</i> on medical Web sites					
c. Look for information <i>about high blood pressure</i> on medical Web sites					
d. Print information from PLISTAZ.com to discuss with your doctor					

Q21. [Health Information Seeking – Source (HMTS)]

Have you looked for health or medical information from any of the following sources within the past 12 months? (Check all that apply)

Offline Sources

- Books, magazines, brochures, or other printed materials
- Family member, friend, or co-worker
- Health care provider
- Library or community center
- Telephone information number (1-800-Number)

Online Sources

- Search Engine (examples: Google, Bing)
- Health and medical Web site (examples: WebMd, MedlinePlus)
- Product Web site (example: Lipitor.com)
- Government organization Web site (example: National Institutes of Health)
- Non-profit organization Web site (examples: AARP, American Heart Assoc.)
- Commercial organization Web site (example: Merck, Novartis)
- Health insurance Web site (examples: Cigna, BlueCross and BlueShield)

- Other: _____
- Did not look or go anywhere
-

Q22. [Illness Information Seeking (Knowledge Proxy)]

In the past 12 months, how often did you use the Internet to look for health or medical information about high blood pressure or treatments for high blood pressure?

- Once a week
- Once a month
- Every few months
- Less often
- Never

Q23. [Mobile Phone or Device Ownership]

Do you own any of the following devices? (Check all that apply)

- Mobile phone
- Smart phone or PDA (i.e., iPhone, Blackberry, Droid, iPod Touch)
- Tablet computer (i.e., iPad)
- None of the above

Q24. [Web Navigation Skills]

We would like to know more about your Internet skills. For each statement below, please tell us to what extent you agree or disagree with the statement.

[Q24A.] I am extremely skilled at using the Web.

1	2	3	4	5	6	7
Strongly Disagree						Strongly Agree

[Q24B.] I consider myself knowledgeable about good search techniques on the Web.

1	2	3	4	5	6	7
Strongly Disagree						Strongly Agree

[Q24C.] I know less about using the Web than most users.

1	2	3	4	5	6	7
Strongly Disagree						Strongly Agree

[Q24D.] I know how to find what I am looking for on the Web.

1	2	3	4	5	6	7
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: PLISTAZ.com)				
Medical Web sites (example: WebMD.com)				
Online communities for people with high blood pressure (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 blood pressure?

- 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 blood pressure?

- 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 blood pressure? 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.

PLISTAZ is not a real product and is not available for sale. Please see your healthcare provider for questions about high blood pressure.

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