

# **Phase 2 Acid Reflux 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
- Acid Reflux → [Continue]
- Crohn's Disease
- Diabetes
- None of the above

### **S2. [Illness Diagnosis #2]**

Do you still have acid reflux?

- Yes → [Skip to Q-AR1]
- No → [Continue to S3]

### **S3. [Illness Diagnosis #3]**

Have you taken any medication for acid reflux in the past 12 months?

- Yes → [Continue]
- No → [Terminate]

The next few questions ask about acid reflux. The purpose of these questions is to find out what most people know and understand about acid reflux. 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-AR1. [Acid Reflux Knowledge #1]**

**Which of the following is a common symptom of acid reflux?**

- Heartburn
- Loss of appetite
- Mouth sores
- Jaw pain
- Don't know

**Q-AR2. [Acid Reflux Knowledge #2]**

**Which of the following is another name for acid reflux?**

- Esophageal manometric disease (EMD)
- Acid pump inhibitor (API)
- Lactic acid (LA)
- Gastroesophageal reflux disease (GERD)
- Don't know

**Q-AR3. [Acid Reflux Knowledge #3]**

**Acid reflux occurs when acid leaks into the:**

- Liver
- Kidney
- Arteries
- Esophagus
- Don't know

**Q-AR4. [Acid Reflux Knowledge #4]**

**Which of the following is a possible way to improve symptoms of acid reflux?**

- Avoid alcohol
- Increase amount of sleep
- Gargle
- Take a hot shower
- 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 FENTIVA?**

Yes

No → [Terminate]

### Q2. [Drug Knowledge (indication, illness)]

**What condition does FENTIVA treat?**

Acid Reflux / GERD

Stomach Ulcers

Upset Stomach

Constipation

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

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

The pill was a long blue capsule

The pill was a small green circle

The pill was a small white circle

The pill was a long tan capsule

I did not see the pill

### Q4. [Benefit Recall]

**What are the benefits of FENTIVA?**

(open ended)



**Q8. [Risk Recall]**

**What are the side effects and negative outcomes of FENTIVA?**

(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 FENTIVA, 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 FENTIVA 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 FENTIVA. Even if you think a statement is true, please select it only if it was mentioned on the site.

<b>[RANDOMIZE ORDER]</b>	<b>Mentioned on Web Site</b>	<b>Not Mentioned on Web Site</b>
a. A side effect of FENTIVA is nausea.	x	
b. People taking FENTIVA may be at higher risk for wrist, hip, or spine fractures.	x	
c. People who have liver disease may need special tests when taking FENTIVA.	x	
d. A side effect of FENTIVA is difficulty swallowing.		x
e. Women who are nursing should tell their doctor before taking FENTIVA.	x	
f. Patients taking FENTIVA may be at higher risk for stomach ulcers.		x
g. In rare cases, FENTIVA can cause kidney disease.		x
h. Patients who have a history of high cholesterol should not take FENTIVA.		x

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

This Web site had a video that showed how FENTIVA 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 FENTIVA?**

- Yes
- No









**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 FENTIVA					
b. Ask your doctor about getting a sample of FENTIVA					
c. Ask your doctor to prescribe FENTIVA					
e. Join an online community or support group <i>for people with acid reflux</i>					
f. Join an online community or support group <i>sponsored by FENTIVA</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 FENTIVA					
b. Look for information <i>about FENTIVA</i> on medical Web sites					
c. Look for information <i>about acid reflux</i> on medical Web sites					
d. Print information from FENTIVA.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 acid reflux or treatments for acid reflux?**

- 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?

<b>[RANDOMIZE ORDER]</b>	<b>Not at all</b>	<b>A little</b>	<b>Some</b>	<b>A lot</b>
Drug Web sites (example: FENTIVA.com)				
Medical Web sites (example: WebMD.com)				
Online communities for people with acid reflux (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 acid reflux?

- 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 acid reflux?

- 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 acid reflux? 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.

FENTIVA is not a real product and is not available for sale. Please see your healthcare provider for questions about acid reflux.

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