

**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.

First, we will ask you a few health-related questions. Next, we will let you explore a Web site about a 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 Web Site Instruciones]
- 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]

S4. [Test Video Capabilities]

During the study, you may be asked to watch a video. To make sure you have the right software, please watch the test video below and answer the following question.

[EMBEDDED VIDEO]

Which word appeared in the video?

- Green → [Continue]
- Blue → [Terminate]
- Red → [Terminate]
- Yellow → [Terminate]
- I could not see the video → [Terminate]

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 review the site carefully and be sure to:

- Turn up your speakers
 - Watch any videos
 - Click any links to other pages or Web sites
- Carefully read the information on the homepage

Once you finish, please close the Web site and click *Next* to continue with 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. [Risk Info Exposure]

FENTIVA.com had information about FENTIVA's benefits and risks. How much of the risk information did you read?

- All of it (100%)
- Most of it (50-99%)
- Some of it (1-49%)
- None of it (0%)

Q4. [Benefit Recall]

What are the benefits of FENTIVA?

(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 FENTIVA, 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 FENTIVA did help a person's acid reflux, how effective would FENTIVA be?

1 2 3 4 5 6
Would help acid reflux very little Would help acid reflux a lot

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

Please check which of the following were mentioned on the Web site as benefits of taking FENTIVA. 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. FENTIVA decreases the amount of acid produced in the stomach.	x	
b. FENTIVA can provide relief from heartburn.	x	
c. FENTIVA needs to be taken only once a week.	x	
d. FENTIVA stops your stomach from producing acid.		x
e. FENTIVA can provide relief from upset stomach.		x
f. FENTIVA must be taken with over-the-counter antacids.		x
g. FENTIVA is a controlled release proton pump inhibitor.	x	
h. FENTIVA eliminates stomach ulcers.		x

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 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 FENTIVA. 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. 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-VT1. [Awareness of Special Feature]

Which of the following features appeared on the FENTIVA Web site?

- Video showing how FENTIVA works
- Video of a patient who has used FENTIVA
- Video of a doctor who recommends FENTIVA
- None of the above

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

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

[IF ‘Video showing how FENTIVA works’ TO Q-VT1] Did you watch this video about FENTIVA?

- Yes
- No

Q-V3. [Perceived Visual Accuracy]

[IF ‘Video showing how FENTIVA works’ TO Q-VT1] How likely or unlikely is it that this video accurately shows how FENTIVA works in real people?

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

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

[IF ‘Video showing how FENTIVA works’ TO Q-VT1] After watching the video, were you more confident or less confident that FENTIVA 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 FENTIVA'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 FENTIVA?
(open ended)

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

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

Q-T2. [Exposure to Special Feature - Testimonial]

[IF 'Video of a patient who has used FENTIVA' to Q-VT1] Did you watch this video about FENTIVA?
Yes
No

Q-T3. [Perceived Testimonial Honesty]

[IF 'Video of a patient who has used FENTIVA' TO Q-VT1] How likely or unlikely is it that the video shows a real patient?

1 2 3 4 5 6 7
Extremely Extremely
Unlikely Likely

Q-T4. [Perceived Testimonial Accuracy]

[IF 'Video of a patient who has used FENTIVA' TO Q-VT1] How likely or unlikely is it that most patients will have the same experience as the patient in the video?

1 2 3 4 5 6 7
Extremely Extremely
Unlikely Likely

Q-T5-A. [Testimonial Effect on Drug Benefit Perceptions]

[IF YES TO Q-T2] After watching the video, were you more confident or less confident that FENTIVA will be effective?

1 2 3 4 5
Less confident No change More confident

Q-T5-B. [Testimonial Effect on Drug Risk Perceptions]

[IF YES TO Q-T2] After watching the video, were you more concerned or less concerned about FENTIVA’s side effects and negative outcomes?

1 2 3 4 5
Less concerned No change More concerned

Q-T6. [Reason for Not Watching Testimonial]

[IF NO TO Q-T2] Why didn’t you watch this video about FENTIVA?

(open ended)

*******END TESTIMONIAL QUESTIONS*******

The next few questions ask about FENTIVA’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 acid reflux.

Q12. [Drug Balance of Risks / Benefits]

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

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.

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

b. The Web site clearly communicated the risks of FENTIVA.					
--	--	--	--	--	--

Q13. [Web Site Balance of Risks / Benefits]

Please think about how the risks and benefits of FENTIVA 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				More emphasis on benefits		

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>					

Unlikely

Likely

Q20. [Site Skepticism]

How skeptical or not skeptical are you about the information about FENTIVA presented on this Web site?

1

2

3

4

5

6

7

Not at all
Skeptical

Extremely
Skeptical

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

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

Family and friends				
Doctors, nurses, and healthcare providers				
Food and Drug Administration (FDA)				
Pharmaceutical companies				

Q34. [Illness Knowledge - Subjective]

In general, how much do you know about acid reflux? Would you say you know:

- Nothing at all
- Only a slight amount
- Some
- A good bit
- A lot

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!