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)

[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.

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

peo	bl	е

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 h	nelp 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.	х	
b. FENTIVA can provide relief from heartburn.	х	
c. FENTIVA needs to be taken only once a week.	Х	
d. FENTIVA stops your stomach from producing acid.		Х
e. FENTIVA can provide relief from upset stomach.		х
f. FENTIVA must be taken with over-the-counter antacids.		Х
g. FENTIVA is a controlled release proton pump inhibitor.	Х	
h. FENTIVA eliminates stomach ulcers.		х

Q8. [Risk Re	ecall]				
What are th	ne side effects and	d negative outco	mes of FENTIVA	۱?	
(ор	en ended)				
[DISPLAY Q	9 AND Q10 ON TH	IE SAME SCREEN]		
When consi	dering a new med	licine, most peop	le ask two ques	stions:	
	this medicine cau does cause side e	•		effects be?	
The questio	ns below ask abo	ut these two idea	s.		
Q9. [Percei	ved Risk - Likeliho	od of Risk]			
	nionIf 100 peop Please enter a nu	•	-	have any s	ide effects or negative
people					
Q10. [Perce	ived Risk - Magni	tude of Risk]			
	nionIf FENTIVA o	did cause a perso	on to have side	effects or n	egative outcomes, how
1	2	3	4	5	6

Very

serious

Not at all

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]	Mentione d on Web Site	Not Mentione d 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 factures.	Х	
c. People who have liver disease may need special tests when taking FENTIVA.	Х	
d. A side effect of FENTIVA is difficulty swallowing.		х
e. Women who are nursing should tell their doctor before taking FENTIVA.	х	
f. Patients taking FENTIVA may be at higher risk for stomach ulcers.		х
g. In rare cases, FENTIVA can cause kidney disease.		Х
h. Patients who have a history of high cholesterol should not take FENTIVA.		х

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]

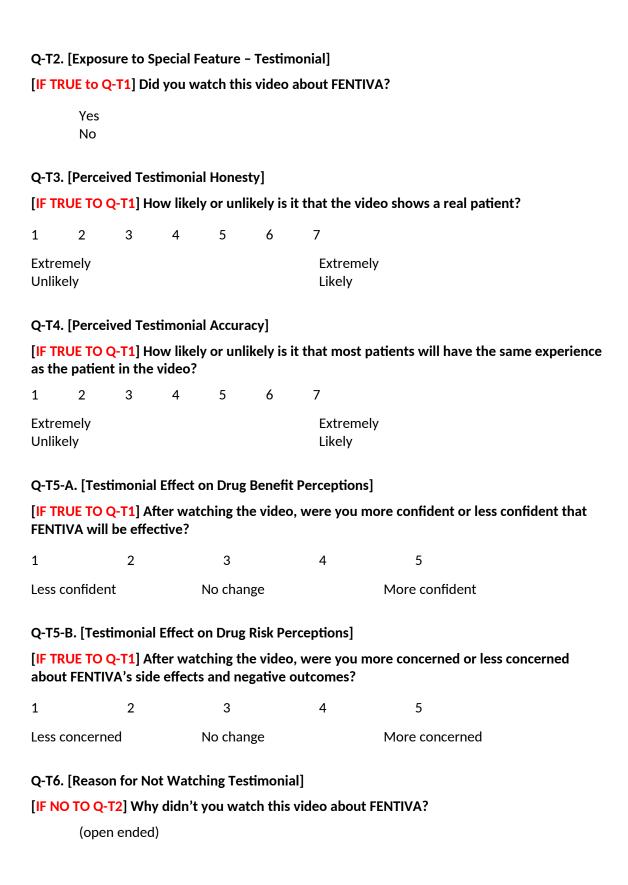
[IF TRUE TO Q-V1] Did you watch this video about FENTIVA?

Yes

No

Q-V3.	[Perceiv	ed Visua	al Accur	acy]			
[IF TRUE TO Q-V1] How likely or unlikely is it that this video accurately shows how FENTIVA works in real people?							
1	2	3	4	5	6	7	
Extren Unlike	•					Extremely Likely	
Q-V4-	A. [Visua	l Effect	on Drug	g Benefit	Percept	ions]	
_	JE TO Q /A will b	_		hing the	video, w	ere you mo	ore confident or less confident that
1		2		3		4	5
Less co	onfident		N	o change	2		More confident
Q-V4-	3. [Visua	l Effect	on Drug	g Risk Peı	rception	s]	
_		_		hing the and nega		-	ore concerned or less concerned
1		2		3		4	5
Less co	oncerned	t	N	o change	2		More concerned
Q-V5.	[Reason	for Not	Watchi	ing Visua	I]		
[IF NO	TO Q-V	2] Why (didn't y	ou watch	n this vic	leo about F	ENTIVA?
	(open	ended)					

Q-T1. [Awareness of Special Feature – Testimonial]							
This Web site had a video of a patient who has used FENTIVA.							
	True False						
****	**** * T2	то т6 ғ	OR TES	TIMONIA	AL ONLY	*******	*



	<i>(</i> - <i>n</i> - 1							
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				Bene	efits			
outweigh risks								
Q18. [Perceived Clarity / Und	derstanding o	of Site]						
Please rate your agreement of	or disagreeme	ent with each o	of the followin	g statements.				
	Strongly	Somewhat	Neither	Somewhat	Strongly			
	disagree	disagree	agree nor	agree	agree			
[RANDOMIZE ORDER]			disagree					
a. The Web site clearly								
communicated the								
benefits of FENTIVA. b. The Web site clearly								
communicated the								
risks of FENTIVA.								
Q13. [Web Site Balance of Ri	isks / Benefit	s]						
Please think about how the	risks and ben	efits of FENTIV	/A were prese	ented on the W	/eb 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								

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

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

symptoms of acid reflux.

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 for people with acid reflux					
f. Join an online community or support group sponsored by FENTIVA					

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</i> FENTIVA on medical Web sites					
c. Look for information about acid reflux on medical Web sites					
d. Print information from FENTIVA.com to discuss with your doctor					

Q16. [Attitudes Toward Drug]

Based on what you learned, please rate FENTIVA. [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]

How likely or unlikely is it that the information	about FENTIVA presented	on this Web site is
true?		

1	2	3	4	5	6	7
Extreme	•					Extremely 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	/
Not at a	II					Extremely
Skeptica	ıl					Skeptical

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 on so on order

- 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 d	consider	myself k	nowled	geable a	bout	good search techniques on the Web.	
1	2	3	4	5	6	7	
Strongly Disagree						Strongly Agree	
[Q24C.] I k	now les	s about	using th	e Web tł	nan m	ost 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:				
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!