***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 Instrucions ]

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 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.**

|  |  |  |
| --- | --- | --- |
| **[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 factures. | 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.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **[RANDOMIZE ORDER]** | **Strongly disagree** | **Somewhat disagree** | **Neither agree nor disagree** | **Somewhat agree** | **Strongly agree** |
| 1. The Web site clearly communicated the *benefits* of FENTIVA. |  |  |  |  |  |
| 1. 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 *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 *about 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

Extremely Extremely

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 Extremely

Skeptical 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 Strongly

Disagree Agree

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

1 2 3 4 5 6 7

Strongly Strongly

Disagree Agree

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

1 2 3 4 5 6 7

Strongly Strongly

Disagree Agree

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

1 2 3 4 5 6 7

Strongly Strongly

Disagree 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) |  |  |  |  |
|  |  |  |  |  |
| 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!