

Phase 1 Seasonal Allergies
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
- Seasonal Allergies → [Continue]
- Crohn's Disease
- Diabetes
- None of the above

S2. [Illness Diagnosis #2]

In the past 12 months, have you suffered from seasonal allergies?

- Yes → [Skip to Web Site Instructions]
- No → [Continue to S3]

S3. [Illness Diagnosis #3]

Have you taken any medication for seasonal allergies in the past 12 months?

- Yes → [Continue]
- No → [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 turn up your speakers and review the site carefully.

Once you finish, please close the Web site window and click Next to continue with the study.

[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 GLISTELL?

Yes

No → [Terminate]

Q2. [Drug Knowledge (indication, illness)]

What condition does GLISTELL treat?

Seasonal Allergies

Indoor Allergies

Bacterial Infections

Upper Respiratory Infections

Q3. [Risk Info Exposure]

GLISTELL.com had information about GLISTELL'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%)

P-RB4. [Risk Information Signal Awareness]

Which of the following statements appeared on the GLISTELL.com home page?

“Please see Important Safety Information below.”

“Please see Important Safety Information by visiting this link.”

“Please see your local pharmacist for Important Safety Information.”

“Please contact KAJ Pharmaceuticals at 1-800-692-2557 for Important Safety Information.”

None of the above statements appeared on the Web site.

[PHASE 1: ASK Q8-11 BEFORE Q4-7]

Q8. [Risk Recall]

What are the side effects and negative outcomes of GLISTELL?

(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 GLISTELL, 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 GLISTELL 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 GLISTELL. 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. In rare cases, GLISTELL can cause a serious allergic reaction.	x	
b. GLISTELL should not be taken by young children (less than two years old) unless directed by a doctor.	x	
c. GLISTELL can make it difficult to concentrate.	x	
d. People with diabetes should not take GLISTELL.		x
e. People with high blood pressure should talk to their doctor before taking GLISTELL.	x	
f. A side effect of GLISTELL is nausea.		x
g. People with liver disease may need different doses of GLISTELL.		x
h. GLISTELL can cause drowsiness.		x

Q4. [Benefit Recall]

What are the benefits of GLISTELL?

(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 GLISTELL, 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 GLISTELL did help a person’s seasonal allergy symptoms, how effective would GLISTELL be?

1 2 3 4 5 6
 Would eliminate very few symptoms Would eliminate all symptoms

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

Please check which of the following were mentioned on the Web site as benefits of taking GLISTELL. 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. GLISTELL contains a long-acting antihistamine.	x	
b. GLISTELL is taken once a day.	x	
c. GLISTELL treats seasonal allergy symptoms.	x	
d. GLISTELL treats indoor allergy symptoms.		x
e. GLISTELL works by boosting your body’s immune system.		x
f. GLISTELL contains a corticosteroid.		x
g. GLISTELL treats symptoms such as nasal congestion.	x	
h. GLISTELL treats symptoms such as blurry vision.		x

The next few questions ask about GLISTELL’s risk 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 seasonal allergies.

c. Ask your doctor to prescribe GLISTELL					
e. Join an online community or support group <i>for people with seasonal allergies</i>					
f. Join an online community or support group <i>sponsored by GLISTELL</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 GLISTELL

b. Look for information *about GLISTELL* on medical Web sites

c. Look for information *about seasonal allergies* on medical Web sites

d. Print information from GLISTELL.com to discuss with your doctor

Q16. [Attitudes Toward Drug]

Based on what you learned, please rate GLISTELL. [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 GLISTELL presented on this Web site is true?

1	2	3	4	5	6	7
Extremely Unlikely						Extremely Likely

Q20. [Site Skepticism]

How skeptical or not skeptical are you about the information about GLISTELL 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 seasonal allergies or treatments for seasonal allergies?

- 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

--	--	--	--	--

Q34. [Illness Knowledge – Subjective]

In general, how much do you know about seasonal allergies? 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 seasonal allergies?

- 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 seasonal allergies?

- 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 are your seasonal allergies? Would you describe them 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.

GLISTELL is not a real product and is not available for sale. Please see your healthcare provider for questions about seasonal allergies.

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