

Testosterone Medication Guide

Cognitive Interview Guide

Color Key:

Purple – Section headings and titles

Black –Text for interviewer to read

Red – Interviewer instructions (not to be read aloud)

Green – Research questions (for interviewer's information, not to be read aloud)

Introduction

Hello, my name is **INTERVIEWER NAME**. I work for Westat, a research company in Rockville, Maryland. Thank you for taking the time to be a part of this study.

Westat is working with the U.S. Food and Drug Administration, or FDA, to see what people think about some prescription drug information they are creating. The FDA is interested in getting opinions about the information I am about to discuss with you. You should have gotten a package in the mail for this study.

Do you have the package we mailed to you with you right now?

IF YES, CONTINUE

IF NO BUT PACKAGE IS NEARBY, ALLOW PARTICIPANT TIME TO GET IT

IF NO AND NOT NEARBY, CONTINUE USING ON-SCREEN VERSION OR ASK IF IT'S OKAY TO EMAIL THE DOCUMENT TO R

Please wait to open the packet until I tell you it is time to start. After you look at the material inside, I will ask you some questions about your thoughts and feelings about the information. Any ideas you have are okay.

Informed Consent

Before we get started, there are a few things I need to tell you. This is a research project, and this interview is voluntary. That means that if you do not want to answer a specific question just tell me and I'll go to the next one. It is okay if you want to stop after we start. Just let me know.

All of your answers and everything you say will be kept secure to the extent permitted by law. This means that we will not share your name or information. Also, we will not link any information to your answers to figure out who you are. The interview will take about 45 minutes and you will get \$50 e-rewards for your time. We would like to record this conversation if you are okay with that. The recording helps us make sure we hear everything you say correctly. Only the people who work on this research project will be able to listen to the recording and see our notes. Your name will not be linked to any of your responses, though we may include quotes that you provide in our reports. The recordings and our notes will be destroyed after we finish the project.

IF FDA STAFF ARE ON THE PHONE: I also want you to know that a couple other people from the FDA who work on this research project are listening to this interview to take notes as we talk.

Before we start, do you have any questions? Do you agree to be interviewed? Is it okay with you if I record the interview?

TURN ON RECORDER. The date and time is _____. Now that I am recording, I want to ask again, is it okay if I record this interview?

Background Questions

Before we talk about the information I mailed to you, I have a few questions.

Have you ever heard of a Medication Guide?

INTERVIEWER NOTE: A “Medication Guide” is what patients receive at the pharmacy.

- **IF YES**, Have you seen one? How would you describe a Medication Guide? What kind of information does it include? Where do you get a Medication Guide?
- **IF NO**, If you had to guess, what type of information do you think a Medication Guide might include? Where do you think you get a Medication Guide?

Now please open the envelope we sent you in the mail. Do you see a piece of paper titled “Medication Guide” for Androgel? Please take a few minutes to look at it now. When you are done, I have some questions for you about the information.

CHECK IN AFTER 5 MINUTES. ALLOW 2-3 MORE MINUTES IF NEEDED.

CONCURRENT OBSERVATIONS/INSTRUCTIONS

NOTE ANY OF THE FOLLOWING BEHAVIORS TO RECORD IN NOTES OR PROBE ON RETROSPECTIVELY:

- Any verbal reaction to the introductory text.
- Any verbal expressions of confusion, surprise, discomfort, offense. Note which statements evoked any of these reactions.

RETROSPECTIVE GENERAL PROBES

TO BE ADMINISTERED AFTER RESPONDENT COMPLETES HIS/HER REVIEW.
SHOW GUIDE ON SCREEN AS NEEDED TO AID DISCUSSION.

RESEARCH QUESTIONS

Is the guide clear and understandable?

What is the main safety message that participants get from the guide?

Is the guide effective in conveying the knowledge of the signs and symptoms in children and women when they come in direct contact with Androgel 1%?

Does the guide provide useful information about how to use Androgel 1% to avoid accidental exposure to women and children?

Do participants recognize the call to action of stopping use of Androgel 1% and calling their healthcare provider if they see signs or symptoms in a child or woman that may have been exposed to the medication?

Is the general layout appealing?

INTRODUCTORY TEXT

Thank you for reading that information. Now I'm going to ask you some questions about it. I want you to know that I did not develop this guide, so please give me your honest opinion about it—you will not hurt my feelings.

First, just tell me your overall thoughts about the guide.

What do you like about it?

What don't you like?

How easy or difficult is it to understand this guide? Is there anything confusing or unclear? Do you think you would need your doctor to help explain any parts of the guide?

DESIGN AND LAYOUT

What do you think of the way the guide is set up?

- Is it easy to read?

- Does the order of the information make sense?

What do you think about the picture on page 3? What is this a picture of?

- Do you think it goes with the information?

Would you say the amount of information in this guide is too little, just right, or too much? What makes you say that?

CONTENT

Now let's talk about what the guide has to say.

In your own words, what is the overall, main message that the guide is trying to tell you?

- What, if anything, is it asking you to do?
- What is the most important message?
- Is the most important information easy to find?
- Is the most important information in the place where it should be?
- Of all the things you read in this guide, what are the most important things to put on the front page?

Is any of this information new to you? Which parts?

Based on this information, how would you use this medication?

Based on this information, what would you say are the most serious risks of taking Androgel 1%? **TO THEMSELVES OR OTHER PEOPLE.**

- Can Androgel transfer from your body to others? (Yes/No/I don't know)

In your own words, what might be noticed in a child who comes into contact with this medication? **NOTE IF R RECALLS THE INFORMATION RIGHT AWAY OR HAS TO LOOK FOR IT**

In your own words, what might be noticed in a woman who comes into contact with this medication? **NOTE IF R RECALLS THE INFORMATION RIGHT AWAY OR HAS TO LOOK FOR IT**

Does the guide clearly explain what might happen to a child or a woman who comes into contact with this medication?

- **IF YES**, Can you tell me what about the guide makes you say it was clear?
- **IF NO**, Can you say more about what wasn't clear?

IF NOT MENTIONED: I noticed you didn't mention [sign or symptom] for a [child or woman]. Why is that? Could that information be stated more clearly?

How much contact with the medication do you think a child or woman would need to show these signs or symptoms?

What would you do if a child or woman accidentally touched your skin where you had applied this medication?

What would you do if a child or woman started to show signs or symptoms described in this guide?

How easy or difficult do you think it would be to remember the information in this guide about what might happen to a child or a woman who comes into contact with this medication? IF DIFFICULT, What would make it easier for you to remember this information?

After reading this guide, do you have any questions about this medication? IF YES, What are they?

IMPACT

If your doctor prescribed Androgel 1% for you and gave you this guide, what would you do with it? IF NEEDED, Throw it away, keep it for a day or two, keep it until finished with the prescription, keep it for future reference, etc. What is it about the guide that would make you do that?

- IF THROW AWAY, What would make this medication guide more worth keeping?

If you were prescribed Androgel 1%, how helpful would this guide be to you? Please respond on a scale of 1 to 5 where 1 is not at all helpful and 5 is extremely helpful.

- What makes you say {PARTICIPANT'S SCALE NUMBER}?

If you are ever prescribed Androgel 1%, will you do anything differently with this medication compared to other types of medication? IF YES, What would you do differently?

IF NEEDED, How would you store this medication?

If you had more questions about Androgel 1%, what would you do? IF NEEDED, Would you talk with your doctor, look for information online, or something else?

- Where would you look online? Would you visit the website listed on the bottom of page 2? Why?

WRAP-UP

Do you have any other suggestions for improving the guide?

- Is there any information that is NOT needed or can be removed? **IF YES**, What information?
- Is there any information that could be added? **IF YES**, What information?
- Is there anything that could be stated more clearly? **IF YES**, What could be stated more clearly?

PROBE ON ANY OUTSTANDING ISSUES FROM OBSERVATION (INFORMATION THAT R SEEMED CONFUSED ABOUT).

Closing

IF OBSERVERS ARE PRESENT, CHECK TO SEE IF THEY HAVE FURTHER QUESTIONS.

Those are all the questions I have for you. Is there anything we haven't talked about that you would like to tell me?

DISCUSS ANY RESPONDENT COMMENTS.

Thank you for your time.

STOP TAPE RECORDER.