

Questionnaire, Toll-Free 2 Study

Questionnaire will be administered via Internet.

- Informed consent procedures must be completed prior to beginning study
- Participants will be blind to FDA's sponsorship

Section I. Interview.

Thank you for agreeing to participate in this study today.

This study is about advertising for new products. You will see four ads and then answer questions about what you've seen. The study will take about 20 minutes.

[PROGRAMMER: Order of filler ads to be determined by pretest]:

1. 30-second non-DTC filler ad 1
2. 30-second unrelated DTC ad
3. 30-second non-DTC filler ad 2
4. ~60-second appropriate Zintria ad]

Now please answer the following questions.

Q1a. Do you recall seeing an ad for [unrelated DTC product]?

Yes

No

I'm not sure

Q1b. Do you recall seeing an ad for Zintria?

Yes

No [If "no," terminate]

I'm not sure [If "not sure," terminate]

Q2. How well do you think Zintria would or would not work for you?

Extremely Well

Quite Well

Moderately Well

Somewhat Well

Not Well At All

Q3. How safe or not safe do you think Zintria is?

- Extremely Safe
- Quite Safe
- Moderately Safe
- Somewhat Safe
- Not at All Safe

Q4. How likely or not likely would you be to lower your blood pressure if you took Zintria?

- Not at All Likely
- Somewhat Likely
- Moderately Likely
- Quite Likely
- Extremely Likely

Q5. How risky or not risky do you think Zintria is?

- Not at all Risky
- Somewhat Risky
- Moderately Risky
- Quite Risky
- Extremely Risky

Q6. **(Behavioral Intention)** Please rate how likely or unlikely you are to do each of the following behaviors [PROGRAMMER: *randomize*]

	Very Likely	Somewhat Likely	Neither Likely nor Unlikely	Somewhat Unlikely	Very Unlikely
a. Talk to your doctor about Zintria					
b. Ask your doctor about getting a sample of Zintria					
c. Look for more information about Zintria					
d. Ask your doctor to					
OMB Control No:					

Zintria					
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Q7a. **(Recall of risks)** Answer these questions as best you can based on the information in the ad for Zintria.

[PROGRAMMER: *randomize*]

	True	False
a. Taking some kinds of over-the-counter cough medicines at the same time as taking Zintria increases your risk of having a heart attack.		
b. Zintria may cause excitability.		
c. If you have a very slow heart rate, you should not take Zintria.		
d. Zintria may cause you to have blurry vision.		
e. One of the most common side effects is tiredness.		
f. Antibiotics may not work as well if you use Zintria at the same time.		
g. You should have regular eye exams when you take Zintria.		
h. One of the most common side effects is nausea.		

Q7b. **(Comprehension of risks)**

Please choose a response based on the information in the ad.

[PROGRAMMER: *randomize items and item responses*]

- i. Why should you NOT stop taking Zintria suddenly?
 - a. You may have unusual changes in behavior
 - b. Your eyes will have trouble adjusting to the change in pressure
 - c. You may have a temporary loss of coordination
 - d. You may experience chest pain

- ii. When you first take Zintria, why should you avoid activities that require you to be alert?
 - a. You may have a temporary loss of coordination
 - b. A common side effect of Zintria is dizziness
 - c. A common side effect of Zintria is nervousness
 - d. You may faint

- iii. Why might you have blurry vision when taking Zintria?
 - a. Zintria lowers the pressure in the eye
 - b. Zintria increases the chance of chronic dry eye
 - c. Zintria lowers the concentration of red blood cells in the eye
 - d. Zintria increases sensitivity to light

Q8a. **(Recall of benefits)** Answer these questions as best you can based on the information in the ad for Zintria.

[PROGRAMMER: *randomize*]

	True	False
a. You take it once a day.		
b. Zintria helps lower your blood pressure.		
c. You take it only once a month.		
d. Zintria can reduce your cholesterol level.		
e. Zintria can reduce your risk of having a stroke.		
f. Zintria is the only high blood pressure medication approved to treat children.		
g. Zintria is proven to help prevent heart attacks.		

Q8b. **(Comprehension of benefits)**
Please choose a response based on the information you learned in the ad.

[PROGRAMMER: *randomize items and item responses*]

- i. What advantage does Zintria have over other treatments for this condition?
 - a. Zintria is taken only once a month.
 - b. Zintria is approved to treat more than one type of high blood pressure
 - c. Zintria helps lower cholesterol
 - d. Zintria helps you lose weight

- ii. Why would your doctor prescribe Zintria for you?
 - a. To increase my blood circulation.
 - b. To reduce the risk of liver damage.

- c. To reduce the risk of stroke.
- d. To decrease my joint pain.

Q9. **(Confusion between statement and adequate provision)** In the Zintria ad, there were some words written on the screen. Please tell us as much as you can remember about this information. (open-ended)

Codes:

- 0 No mention of any contact information
- 1 Mention of adequate provision information only
- 2 Mentioned some content of toll-free statement but confused it with adequate provision information
- 3 Some content of toll-free statement/ not confused with adequate provision (adequate provision information can be mentioned also but it is clear that they are distinct)
- 4 Full content of statement/ not confused with adequate provision

Q10. Which, if any, of the following statements appeared in the ad? You may select more than one.

[PROGRAMMER: *randomize*

Include ONLY the toll-free statement that each participant saw, either a. OR b., NOT both]

- a. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.
- b. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch
- c. 800-555-ZINT
- d. Clinical trials involved men and women over the age of 18 and were conducted up to 12 months.
- e. www.zintria.com
- f. Individual results may vary.

[PROGRAMMER: *show the correct statement while Questions 11-14 appear*]

Q11. What does this statement mean to you? (open-ended)

Codes to be determined during pilot testing

Q12. How understandable is this statement?

- Extremely understandable
- Quite understandable

Moderately understandable
Somewhat understandable
Not at all understandable

[PROGRAMMER: *Include Q12a. only in pilot testing*]

Q12a. Why did you select that answer in the previous question?

(open-ended)

Q13. How confusing is this statement?

Extremely confusing
Quite confusing
Moderately confusing
Somewhat confusing
Not at all confusing

Q14. How clear is this statement?

Extremely clear
Quite clear
Moderately clear
Somewhat clear
Not at all clear

Q15. Have you ever had a serious side effect from a prescription drug?

Yes
No
I'm not sure

Q16. If you had a serious side effect from a prescription drug you were taking, how likely would you be to do each of the following things? {randomize options; j always last}

	Very Likely	Somewhat Likely	Neither Likely nor Unlikely	Somewhat Unlikely	Very Unlikely
a. Call your doctor					
b. Call FDA					
c. Treat with another drug					

d. Go to the emergency room					
e. Call the poison control center					
f. Talk to a family member					
g. Talk to a friend					
h. Talk to a pharmacist					
i. Call the drug company					
j. Do nothing					

Q17. If you had a serious side effect from a drug you were taking, which of the following would you do **first**?

[PROGRAMMER: *randomize options; j always last*]

a. Call your doctor
b. Call FDA
c. Treat with another drug
d. Go to the emergency room
e. Call the poison control center
f. Talk to a family member
g. Talk to a friend
h. Talk to a pharmacist
i. Call the drug company
j. Do nothing

Q18. Are you currently taking any prescription drugs for high blood pressure?

- Yes
- No
- I'm not sure

Q19. Have you ever seen any advertising for Zintria before today?

Yes
No
I'm not sure

The following questions may already have been obtained through KN—as long as we have this information in variable form in SPSS, we don't have to ask them again

Q20. Please insert your date of birth.

Q21. Please check your highest level of education.

Some high school
High school graduate
Some college
College graduate
Some graduate experience
Advanced degree (e.g., M.S., M.D., J.D., Ph.D.)

Q22. Are you:

- Hispanic or Latino
- Not Hispanic or Latino

Q23. Which of these best represents your race? You may choose one or more. Would you say that you are:

- American Indian or Alaska Native
- Asian
- Black or African-American
- Native Hawaiian or Other Pacific Islander
- White

Q24. Gender

- Male
- Female

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