

Many people experience mild side effects when starting to take a new product or medication. For example, you may have had mild side effects when you first started taking hormonal contraceptives or medication to prevent malaria. Mild side effects could even occur when you start using a new product like a face cream. Likewise, the first few doses of your study gel or tablets may make you feel unwell, but when you continue to use your tablets or gel, these side effects often go away. This handout provides information on what side effects you might experience and how to deal with them. Please remember:

- A more complete list of side effects is provided in the informed consent form; please let the study staff know if you need another copy of that form.
- Many participants have few or no side effects when they start study product.
- Some of the side effects listed below can happen to people who are not in the study and can happen to study participants for reasons other than the study product. Please do not stop taking your study product if you experience any of the minor side effects below—instead come to the clinic for an exam to get treated for the side effect and the clinician can assess if it is related to the study product.

For those who experience side effects when starting study product, side effects tend to be minor and don't last very long, often resolving within two weeks as women continue to take their gel or tablets.

In the VOICE Study, some participants have experienced the following side effects;

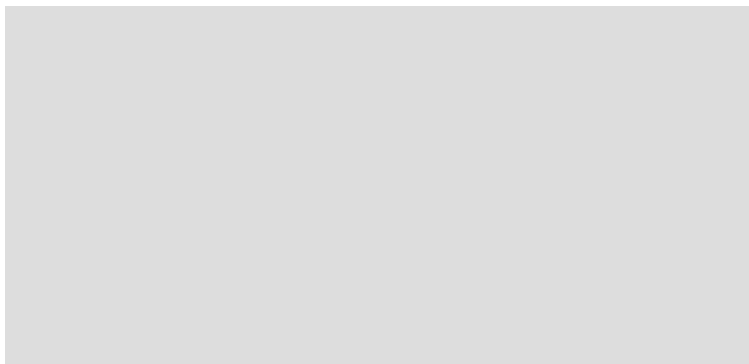
- 1) Headache:
  - a. This tends to be mild and can be relieved with simple pain relief medication that is available without a prescription from your pharmacy or supermarket.

- b. If you experience a headache soon after taking your product, try taking the product before bed time so it doesn't affect your daily activities.
- 2) Body pain or weakness:
  - a. If you experience weakness or pain that is unusual for you, let the study staff know immediately so they can help you.
- 3) Diarrhea:
  - a. Diarrhea is a common complaint and may be due to reasons other than study product such as spoiled food or drinking unclear water.
  - b. This does not typically require stopping your study gel or tablets. If diarrhea continues, make sure you increase your fluid intake to stay hydrated, and let the study staff know.
- 4) Nausea and/or upset stomach:
  - a. If you experience nausea try taking tablets with a meal or before going to bed.
- 5) Women using the gel may feel discomfort or mild itching in the genital area, or leakage of the gel. When inserting the gel push the applicator into the vagina as per the instructions to prevent leakage. If leakage occurs, you can use the panty liners provided to help you feel comfortable. Inserting the gel before bedtime may also help.

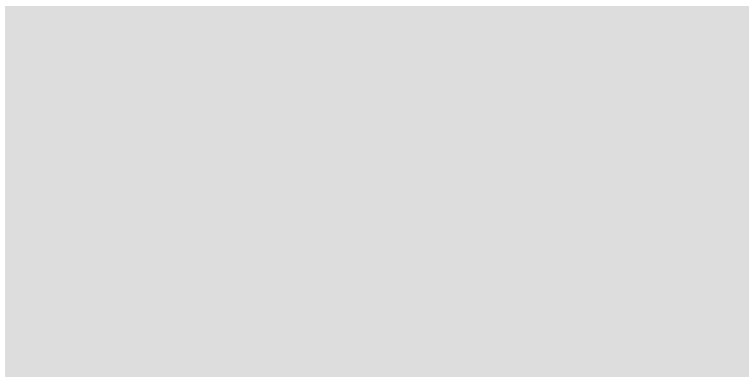
Please remember:

- Most side effects, especially those mentioned above, tend to happen more during the first few days to a week or two after starting study product and get better with time.
- It is very important that you come back to the clinic for your scheduled follow-up visits to make sure that you are not experiencing any side effects from the study products which would require treatment.

If you have questions about side effects or need more information, please come back to your clinic to see a study clinician:



If you have any immediate questions or concerns, you may also contact:



If your partner or family members have any questions about this research study or the study tablets/gel, please invite them to come to the clinic with you for more information or provide them with the number above.

# The VOICE Study

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What can you expect when you start taking your study product?

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