

PATIENT INFORMATION
XACIATO™ (zah-she-AH-toe)
(clindamycin phosphate)
vaginal gel

Important Information: XACIATO is for intravaginal use only. Do not use in the eyes, mouth, or on your skin.

What is XACIATO?

- XACIATO vaginal gel is a prescription medicine used to treat bacterial vaginal infections in females 12 years of age and older.
- It is not known if XACIATO is safe and effective in children under 12 years of age.

Do not use XACIATO if you are:

- allergic to clindamycin or lincomycin.

Before using XACIATO, tell your healthcare provider about all of your medical conditions, including if you:

- have inflammatory bowel disease, including ulcerative colitis and Crohn's disease.
- are pregnant or plan to become pregnant. It is not known if XACIATO will harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with XACIATO.
- are breastfeeding or plan to breastfeed. The amount of XACIATO which passes into your breast milk is low and is not expected to harm your baby. Talk with your healthcare provider about the best way to feed your baby while using XACIATO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I use XACIATO?

- Use XACIATO exactly as your healthcare provider tells you to use it.
- Use 1 filled applicator of XACIATO in the vagina.
- Do not use any medicine from the tube or applicator more than 1 time. XACIATO is for 1 time (single-use) only.
- Do not use in the eyes, mouth, or on your skin.
- See the **Instructions for Use** at the end of this Patient Information leaflet for more information about how to fill the applicator and use XACIATO.

What should I avoid while using XACIATO?

After you insert XACIATO:

- Do not have vaginal sex or use vaginal products (such as tampons or douches) during treatment with XACIATO and for 3 days after using XACIATO.
- You should not use polyurethane condoms during treatment with XACIATO and for 7 days after using XACIATO. XACIATO may weaken polyurethane condoms and they may not work well for preventing pregnancy or protecting against Human Immunodeficiency Virus (HIV) and other sexually transmitted diseases (STDs). Latex or polyisoprene condoms should be used.

What are the possible side effects of XACIATO?

XACIATO may cause serious side effects, including diarrhea. One type of diarrhea is caused by an infection in your intestines called *Clostridioides difficile*-associated diarrhea (CDAD), which may range in severity from mild diarrhea to colitis that can lead to death. If you have diarrhea after you use XACIATO, call your healthcare provider.

The most common side effects of XACIATO include:

- Yeast infection in your vagina that may require treatment with an antifungal medicine.
- Vaginal discomfort including itching, burning, redness and dryness.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of XACIATO. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store XACIATO?

- Store XACIATO at room temperature between 68°F and 77°F (20°C to 25°C).

Keep XACIATO and all medicines out of the reach of children.

General information about the safe and effective use of XACIATO.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use XACIATO for a condition for which it was not prescribed. Do not give XACIATO to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about XACIATO that is written for health professionals.

What are the ingredients in XACIATO?

Active ingredient: clindamycin phosphate

Inactive ingredients: benzyl alcohol, citric acid monohydrate, poloxamer 407, purified water, sodium citrate dihydrate and xanthan gum

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This Patient Information has been approved by the U.S. Food and Drug Administration.

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