

INSTRUCTIONS FOR USE

XACIATO™ [zah-she-AH-toe]

(clindamycin phosphate vaginal gel 2%)

For vaginal use only. Do not use in the eyes or mouth, or on your skin.

Read these Instructions for Use before you use XACIATO™ and each time you get a refill as there may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

Important Information

- Use XACIATO exactly as your healthcare provider tells you to use it.
- Use 1 filled applicator of XACIATO gel in your vagina.
- **Do not** use any medicine from the tube or applicator more than 1 time. The XACIATO gel is for 1 time (single-use) only.
- **Do not** have vaginal sex or use vaginal products (such as tampons or douches) during treatment with XACIATO gel and for 3 days after using XACIATO gel.
- **Do not** use polyurethane condoms during treatment with XACIATO gel and for 7 days after using XACIATO gel. XACIATO gel may weaken polyurethane condoms. Latex or polyisoprene condoms should be used.
- If you have questions or if your vaginal symptoms do not go away, contact your healthcare provider.

How do I store XACIATO?

- Store XACIATO gel at room temperature between 68°F to 77°F (20°C to 25°C).
- **Do not** store in the refrigerator or freezer.

Store XACIATO gel and all medicines out of the reach of children.

You will need the following included supplies
(see Figure A):

- 1 single use tube containing the XACIATO gel
- 1 empty applicator, to fill and deliver the single dose of medicine.

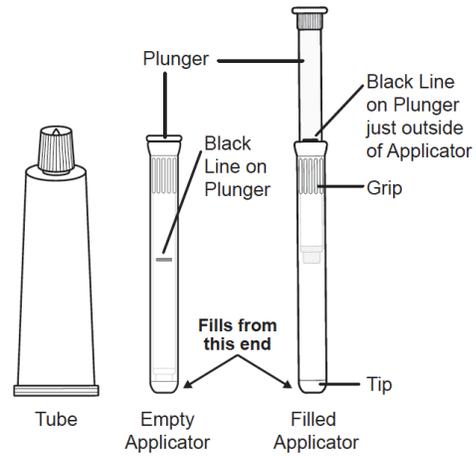


Figure A

Step 1. Remove the applicator and tube from the container box.

Step 2. Open the tube.

- Unscrew the cap from the tube (see Figure B1).
- Puncture the seal on the tube using the pointed tip on the cap by pushing the cap straight onto the tube (see Figure B2).
- **Do not** use the tube if it looks like it has been opened before.
- **Do not** use the tube if the seal is damaged or broken.

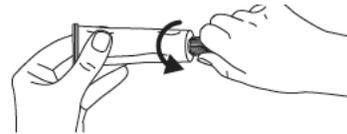


Figure B1

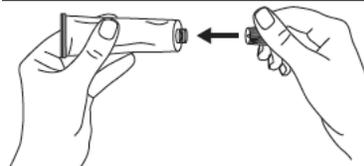


Figure B2

Step 3. Fill the applicator.

- While holding the applicator by the grip, screw the tip of the applicator (other end from the grip) onto the tube until it feels secure (see **Figure C1**).
- Leave plunger inside the applicator.
- Squeeze the tube from the bottom to push the XACIATO gel into the applicator (see **Figure C2**).
- The XACIATO gel will push the plunger up as the applicator fills (see **Figure C3**).
- Continue to fill the applicator until you see the black line on the plunger outside the applicator (see **Figure C4**).
- Unscrew the filled applicator from the tube.

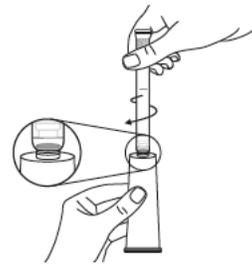


Figure C1

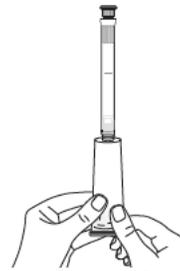


Figure C2

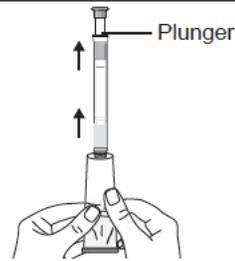


Figure C3

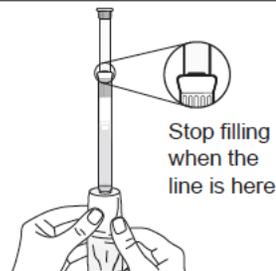
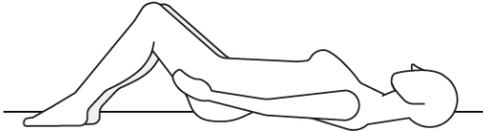
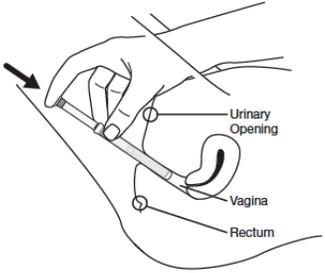
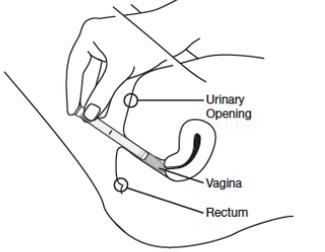


Figure C4

<p>Step 4. Prepare to insert the filled applicator.</p> <ul style="list-style-type: none"> • Lie on your back with your knees bent or in any comfortable position (see Figure D). 	 <p>Figure D</p>
<p>Step 5. Insert the filled applicator.</p> <ul style="list-style-type: none"> • Hold the filled applicator by the grip and gently insert the tip of the applicator into your vagina as far as it will comfortably go (see Figure E). 	 <p>Figure E</p>
<p>Step 6. Push the plunger.</p> <ul style="list-style-type: none"> • While holding the applicator in place, slowly push the plunger until it stops, to release all the XACIATO gel into your vagina (see Figure F). 	 <p>Figure F</p>
<p>Step 7. Remove the empty applicator from your vagina.</p>	
<p>Step 8. Place the used applicator and tube in the container box and throw away (dispose of) in your household trash.</p>	

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This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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