

**PATIENT INFORMATION**  
**PHEXXI® (FEX ee)**  
**(lactic acid, citric acid, and potassium bitartrate) vaginal gel**  
**For Vaginal Use Only**

**What is PHEXXI?**

- PHEXXI is a prescription medicine used to prevent pregnancy in females who can become pregnant and choose to use an on-demand method of birth control.
- PHEXXI is not effective at preventing pregnancy when used **after** vaginal sex.

**How well does PHEXXI work?**

Your chance of getting pregnant depends on how well you follow the directions for using PHEXXI. The better you follow the directions, the less chance you have of getting pregnant. It is very important that you follow the directions carefully **each time** you have vaginal sex.

PHEXXI does not protect against HIV infection or other sexually transmitted infections (STIs).

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

- are pregnant or think you are pregnant. PHEXXI is not for use in pregnant women.
- are breastfeeding or plan to breastfeed. It is not known if PHEXXI passes into your breast milk.

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

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

**How should I use PHEXXI?**

- See the **Instructions for Use** that come with PHEXXI for detailed instructions on the right way to use PHEXXI.
- Use PHEXXI exactly as your healthcare provider tells you to use it.
- PHEXXI must be used **before** vaginal sex.
- PHEXXI comes as a pre-filled single-dose vaginal applicator.
- Insert 1 PHEXXI pre-filled applicator into your vagina and use PHEXXI **within 1 hour before each time** you have vaginal sex. If you do not have vaginal sex within 1 hour of using PHEXXI, you must insert a new PHEXXI pre-filled applicator.
- If you have vaginal sex more than 1 time within 1 hour, you must use a new PHEXXI pre-filled applicator.
- PHEXXI may be used at any time during the menstrual cycle.
- PHEXXI may be used as soon as your healthcare provider tells you it is safe for you to have vaginal sex after childbirth, abortion, or miscarriage.
- PHEXXI may be used with hormonal contraceptives; and latex, polyurethane and polyisoprene condoms. PHEXXI may be used with a vaginal diaphragm. Avoid using PHEXXI with contraceptive vaginal rings.
- PHEXXI may be used with other medicines used in the vagina to treat infections including miconazole, metronidazole and tioconazole.

**What are the possible side effects of PHEXXI?**

**PHEXXI may cause serious side effects, including:**

- **Bladder infection (cystitis) and acute kidney infection (pyelonephritis).** Urinary tract infections are common but can also be serious. You should not use PHEXXI if you have a history of urinary tract infections that keep coming back or other problems with your urinary tract. Call your healthcare provider if you have burning with urination or other signs and symptoms of a urinary tract infection such as: burning feeling when passing urine, urine that looks cloudy, pain in the pelvis, or back pain.
- **Allergic reactions.** Avoid using PHEXXI if you are a female who can become pregnant and are allergic to lactic acid, citric acid, potassium bitartrate or any of the ingredients in PHEXXI; **or** your sexual partners are allergic to any of the ingredients in PHEXXI. Stop using PHEXXI if you have a local vulvovaginal reaction.

**The most common side effects of PHEXXI include:**

- |                           |                                      |                                  |
|---------------------------|--------------------------------------|----------------------------------|
| • vaginal burning         | • discomfort around the vaginal area | • vaginal discharge              |
| • vaginal itching         | • bacterial vaginosis                | • discomfort in the genital area |
| • vaginal yeast infection |                                      | • pain while passing urine       |

These are not all the possible side effects of PHEXXI.

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

**How should I store PHEXXI?**

- Store PHEXXI at room temperature between 68°F to 77°F (20°C to 25°C).
- Store PHEXXI in the original foil pouch.

**Keep PHEXXI and all medicines out of the reach of children.**

**General information about the safe and effective use of PHEXXI.**

Medicines are sometimes used for purposes other than those listed in a Patient Information leaflet. Do not use PHEXXI for a condition for which it was not prescribed. Do not give PHEXXI to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your healthcare provider or pharmacist for information about PHEXXI that is written for health professionals.

**What are the ingredients in PHEXXI?**

**Active ingredients:** lactic acid, citric acid, and potassium bitartrate

**Inactive ingredients:** glycerin, alginic acid, xanthan gum, sodium hydroxide, benzoic acid, and purified water

For more information, go to [www.phexxi.com](http://www.phexxi.com) or call 1-833-EVFM BIO.

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

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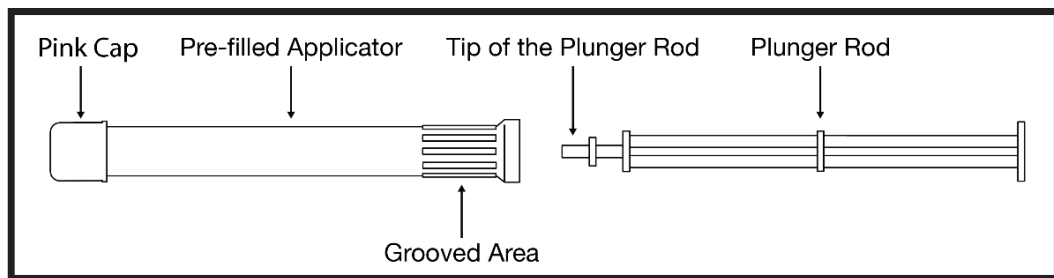
**INSTRUCTIONS FOR USE**  
**PHEXXI® (FEX ee)**  
**(lactic acid, citric acid, and potassium bitartrate)**  
**vaginal gel**

**For Vaginal Use Only**

**These Instructions for Use contain information on how to use PHEXXI vaginal gel.** Make sure that you read, understand, and follow the Instructions for Use before using PHEXXI and each time you get a refill. There may be new information.

**Contents:**

- Each box contains either 3 or 12 foil pouches.
- Each foil pouch contains a pre-filled applicator and plunger rod (see Figure A).
- Each pre-filled applicator contains 1 dose of PHEXXI for 1-time use (single use).



**Figure A**

**Important Information You Need to Know Before Using PHEXXI**

- Use 1 dose of PHEXXI **within 1 hour** before you have vaginal sex.
- A new PHEXXI pre-filled applicator must be used **each time** you have vaginal sex. If you have vaginal sex more than 1 time within 1 hour, **a new PHEXXI pre-filled applicator must be used.**

## Prepare to Use PHEXXI

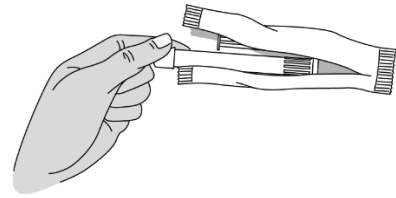
Keep the pre-filled applicator and plunger rod in the foil pouch until you are ready to use PHEXXI.

### Step 1: Wash Your Hands

- Wash your hands with soap and water before opening the foil pouch.

### Step 2: Remove the Pre-filled Applicator and Plunger Rod from the Foil Pouch

- Remove the pre-filled applicator and plunger rod from the foil pouch (see Figure B).



**Figure B**

**Important:** Do not remove the pink cap until instructed in Step 4.

## Insert PHEXXI Gel

### Step 3: Insert the Plunger Rod

- Gently and slowly insert the plunger rod into the pre-filled applicator. Push until you feel the tip of the plunger rod connect to the inside of the pre-filled applicator (see Figure C).
- **Do not** push hard or continue to push after the tip of the plunger rod connects to the inside of the pre-filled applicator. This could cause the gel to go into the pink cap.
- Use a new pre-filled applicator if the gel goes into the pink cap.

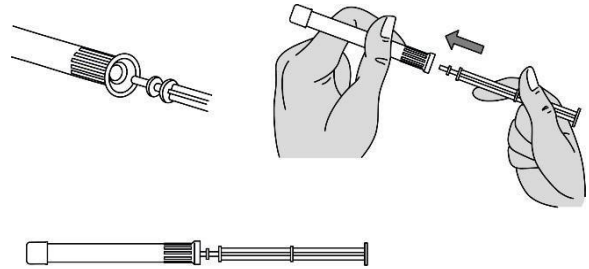


Figure C

### Step 4: Remove the Pink Cap

- After the plunger rod is connected to the pre-filled applicator, remove the pink cap from the pre-filled applicator (see Figure D).
- The extra space between the gel and the end of the pre-filled applicator is normal.
- The pre-filled applicator is now ready for use.

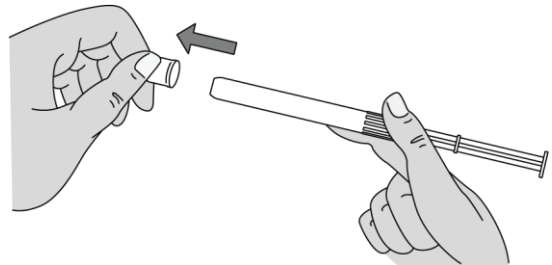


Figure D

### Step 5: Insert the PHEXXI Pre-filled Applicator into the Vagina

- Hold the pre-filled applicator at the grooved area closest to the plunger rod (see Figure E).
- Gently insert the pre-filled applicator into the vagina as far as it will comfortably go while you continue to hold it by the grooved area firmly. This can be done sitting with your knees apart, lying on your back with your knees bent (see

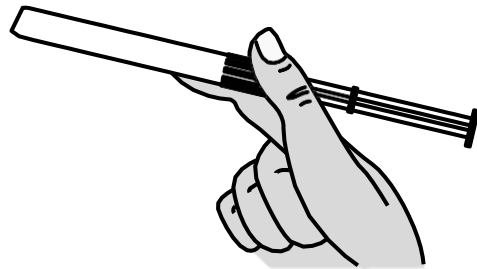


Figure E

Figure F), or while standing with your feet apart or knees bent.

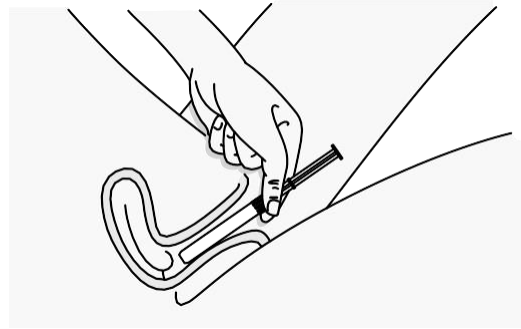


Figure F

### Step 6: Insert PHEXXI Gel

- While the pre-filled applicator is inserted in your vagina, use your index finger to push the plunger rod down until it stops. This is to make sure you receive the entire dose of PHEXXI (see Figure G).
- It is normal for a small amount of gel to be left in the applicator. You will still get the right dose.

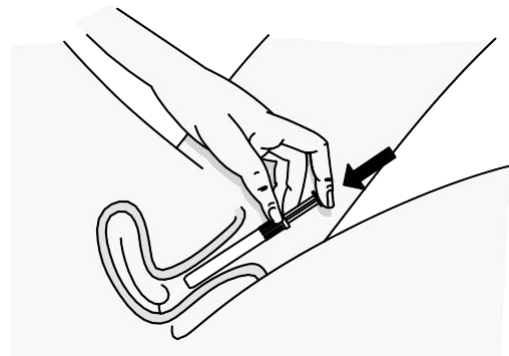


Figure G

### Step 7: Remove the Used PHEXXI Pre-filled Applicator

- Gently remove the plunger rod and pre-filled applicator from the vagina (see Figure H) and throw away (dispose of) the used pre-filled applicator.
- PHEXXI should be used **within 1 hour before each time you have vaginal sex**. Use a new pre-filled applicator if you do not have vaginal sex within 1 hour of inserting PHEXXI gel and you still plan to have vaginal sex.

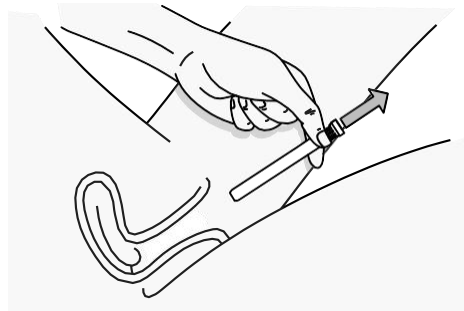


Figure H

## Disposing of PHEXXI

### Step 8: Throw Away (Dispose of) the Used PHEXXI Pre-filled Applicator

- Used PHEXXI pre-filled applicators and caps should be disposed of in the trash. The cap may be a potential choking hazard.

### **Storing PHEXXI**

- Store PHEXXI at room temperature between 68°F to 77°F (20°C to 25°C).
- Store PHEXXI in the original foil pouch.

**Keep PHEXXI and all medicines out of the reach of children.**

These Instructions for Use have been approved by the U.S. Food and Drug Administration.

For more information, including full prescribing information and information on patient safety, go to [www.phexxi.com](http://www.phexxi.com) or call 1-833-EVFM BIO.

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