PHEXX- lactic acid, l-, citric acid monohydrate, and potassium bitartrate gel
Evofem, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use PHEXX® safely and effectively. See full prescribing information for PHEXX.

PHEXX (lactic acid, citric acid, and potassium bitartrate) vaginal gel
Initial U.S. Approval: 2020

INDICATIONS AND USAGE

PHEXX is a combination of lactic acid, citric acid, and potassium bitartrate indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception. (1)
Limitations of Use: PHEXX is not effective for the prevention of pregnancy when administered after intercourse.

DOSAGE AND ADMINISTRATION

- Administer one (1) pre-filled single-dose applicator of PHEXX (5 grams) vaginally immediately before (or up to one hour before) each episode of vaginal intercourse (2.1)
- May use during any part of the menstrual cycle (2.2)

DOSAGE FORMS AND STRENGTHS

Each pre-filled single-dose vaginal applicator delivers 5 grams of gel containing lactic acid (1.8%), citric acid (1%), and potassium bitartrate (0.4%). (3)

WARNINGS AND PRECAUTIONS

- Cystitis and Pyelonephritis: Avoid use in women with a history of recurrent UTI or urinary tract abnormalities (5.1)

ADVERSE REACTIONS

Most common adverse reactions (≥2%) were vulvovaginal burning sensation, vulvovaginal pruritus, vulvovaginal mycotic infection, urinary tract infection, vulvovaginal discomfort, bacterial vaginosis, vaginal discharge, genital discomfort, dysuria, and vulvovaginal pain. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Evofem at toll-free phone 1-833-EVFMBIO or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.
Revised: 12/2024

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

PHEXX is indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.

Limitations of Use

PHEXX is not effective for the prevention of pregnancy when administered after intercourse *[see Dosage and Administration (2.1)].*

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage

Administer one pre-filled applicator of PHEXX (5 grams) vaginally immediately **before** or up to one hour **before** each act of vaginal intercourse. If more than one act of vaginal intercourse occurs within one hour, an additional dose must be applied. Five grams of PHEXX contains 90 mg of lactic acid, 50 mg of citric acid, and 20 mg of potassium bitartrate.

2.2 Timing of PHEXX Use

May use PHEXX during any part of the menstrual cycle. May use PHEXX as soon as it is safe to resume vaginal intercourse after childbirth, abortion, or miscarriage.

2.3 Use of PHEXX with Other Contraceptive Methods

PHEXX may be used concomitantly with hormonal contraceptives; latex, polyurethane, and polyisoprene condoms; and vaginal diaphragms. Avoid PHEXX use with vaginal rings.

2.4 Use of PHEXX with Other Vaginal Products

PHEXX may be used concomitantly with other products for vaginal infections including miconazole, metronidazole, and tioconazole.

3 DOSAGE FORMS AND STRENGTHS

Vaginal gel: 18 mg of lactic acid, 10 mg of citric acid, and 4 mg of potassium bitartrate in each gram (1.8%, 1%, and 0.4%, respectively) of off-white to tan color gel supplied in a pre-filled single-dose (5 grams) vaginal applicator

5 WARNINGS AND PRECAUTIONS

5.1 Cystitis and Pyelonephritis

Among 2804 subjects who received PHEXX in Studies 1 and 2, 0.36% (n=10) reported adverse reactions of cystitis, pyelonephritis, or other upper urinary tract infection (UTI). Of these, one case of pyelonephritis was considered serious and required hospitalization. Avoid use of PHEXX in females of reproductive potential with a history of recurrent urinary tract infection or urinary tract abnormalities.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Cystitis and Pyelonephritis *[see Warnings and Precautions (5.1)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of PHEXX (pre-filled applicator with 5-gram dose) has been evaluated in two clinical trials (Study 1 and Study 2) in 2804 subjects (over 19,000 cycles of exposure). The racial/ethnic distribution was 66% White, 27% Black or African American, 2% Asian, 1% American Indian or Alaska Native, 0.3% Native Hawaiian or Pacific Islander, and 5% other; 32% of the study population was Hispanic. Study 1 included a one-year extension phase where 342 U.S. subjects were exposed to PHEXX for 13 cycles.

Hypersensitivity Reaction

Of the 2804 PHEXX-treated subjects in Studies 1 and 2, one subject reported a suspected drug hypersensitivity. Avoid PHEXX use in females of reproductive potential with suspected hypersensitivity to the ingredients in PHEXX.

The most common adverse reactions (≥10%) in the U.S. population in Studies 1 and 2 (n = 2480) were: vulvovaginal burning sensation (18.0%) and vulvovaginal pruritus (14.5%). The majority of these adverse reactions were mild and few led to discontinuation. Table 1 summarizes the most common adverse reactions (≥2%) reported by subjects using PHEXX in the U.S.

Table 1. Adverse Reactions that Occurred in ≥ 2% of Subjects Who Used PHEXX to Prevent Pregnancy (Studies 1 and 2 – U.S. population only)

Adverse Reaction	PHEXX (N=2480) (%)
Vulvovaginal Burning Sensation	18.0
Vulvovaginal Pruritus	14.5
Vulvovaginal Mycotic Infection*	9.1
Urinary Tract Infection† ‡	9.0
Vulvovaginal Discomfort	9.0
Bacterial Vaginosis	8.4
Vaginal Discharge	5.5
Genital Discomfort	4.1
Dysuria	3.1
Vulvovaginal pain	2.1

* Includes preferred terms (PT) vulvovaginal mycotic infection and vulvovaginal candidiasis.
† Includes PTs urinary tract infection, streptococcal urinary tract infection, Escherichia urinary tract infection, and urinary tract infection bacterial.
‡ Does not include PTs cystitis, kidney infection, and pyelonephritis [see *Warnings and Precautions (5.1)*].

Among subjects who used PHEXX in Studies 1 and 2, 1.6% discontinued from the clinical trials due to an adverse reaction. The most common adverse reactions leading to study discontinuation were vulvovaginal burning sensation (0.7%); and vulvovaginal pruritus and vulvovaginal discomfort (0.1% each).

Adverse Reactions in Male Partners

Among male partners of subjects who used PHEXX for contraception in Study 2, 9.8% (131 of 1330) reported symptoms of local discomfort (burning, itching, pain, and "other"). Of these local discomfort symptoms, 74.7% were mild, 21.4% were moderate, and 3.9% were severe. Two subjects discontinued participation in the study due to male partner symptoms.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There is no use for PHEXX in pregnancy; therefore, discontinue PHEXX during pregnancy. There are no data with the use of PHEXX in pregnant women or animals. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4 percent and 15 to 20 percent, respectively.

8.2 Lactation

Risk Summary

There are no data on the presence of lactic acid, citric acid, and potassium bitartrate or their metabolites in human milk, the effects on the breastfed infant, or the effects on milk production.

8.4 Pediatric Use

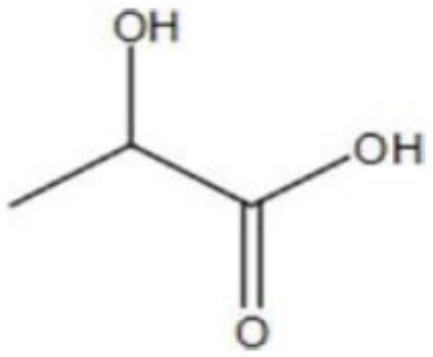
The safety and effectiveness of PHEXX have been established in females of reproductive potential. Efficacy is expected to be the same for post-menarchal females under the age of 17 as for users 17 years and older. The use of PHEXX before menarche is not indicated.

11 DESCRIPTION

PHEXX (lactic acid, citric acid, and potassium bitartrate) is a vaginal gel.

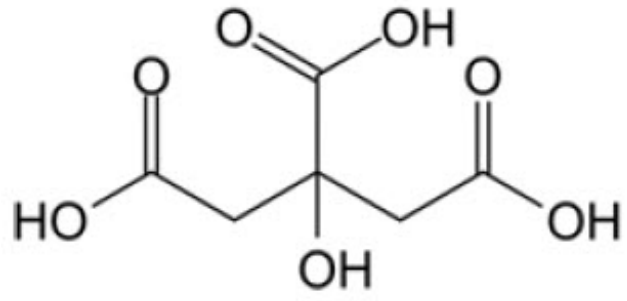
PHEXX is an off-white to tan in color gel of uniform consistency, containing three active ingredients: lactic acid, citric acid, and potassium bitartrate.

The structural formula for lactic acid is:



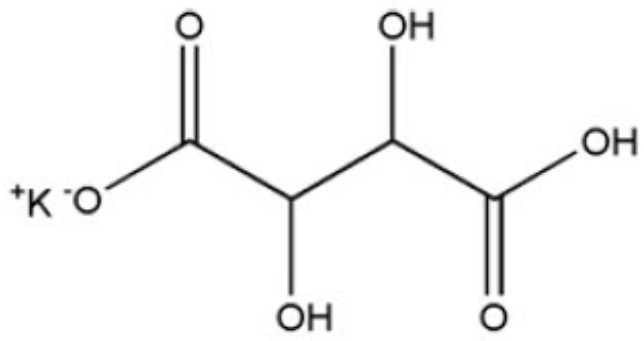
Lactic acid is designated chemically as 2-hydroxypropanoic acid with an empirical formula ofC3H6O3 and a molecular weight of 90.08 g/mol.

The structural formula for citric acid is:



Citric acid is designated chemically as 2-hydroxypropane-1,2,3-tricarboxylic acid with an empirical formula of C6H8O7 and a molecular weight of 192.124 g/mol.

The structural formula for potassium bitartrate is:



Potassium bitartrate is designated chemically as potassium; (2*R*, 3*R*)-2,3,4-trihydroxy-4-oxobutanoate with an empirical formula of $KC_4H_5O_6$ and a molecular weight of 188.177 g/mol.

Each 5 gram dose is provided in a pre-filled single-dose applicator containing lactic acid USP (1.8% w/w), citric acid USP (1% w/w), and potassium bitartrate USP (0.4% w/w). Inactive ingredients present in the gel are: glycerin, alginic acid, xanthan gum, sodium hydroxide, benzoic acid, and purified water.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

In *in vitro* studies, PHEXX produced a normal vaginal pH range (pH 3.5 – 4.5) in the presence of semen. In clinical studies, post-coital testing demonstrated pH < 5 in the majority of subjects, and sperm motility reduction.

12.2 Pharmacodynamics

Pharmacodynamic studies in humans have not been performed.

12.3 Pharmacokinetics

Pharmacokinetic studies in humans have not been performed. Systemic exposures of lactic acid, citric acid, and potassium bitartrate following vaginal administration of PHEXX are not expected to lead to safety concerns.

In vitro studies with commonly used vaginal preparations (miconazole, metronidazole, tioconazole, and a product for maintaining normal vaginal pH) showed no significant effect on the pH or buffering capacity of PHEXX.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Long-term carcinogenicity studies have not been performed with PHEXX.

Mutagenesis

Mutagenic studies have not been performed with PHEXX.

Impairment of Fertility

Reproductive studies have not been performed with PHEXX. Upon discontinuation of PHEXX, pregnancy may occur.

14 CLINICAL STUDIES

The efficacy of PHEXX for the prevention of pregnancy was evaluated in a multi-center, open-label, single-arm clinical trial in the United States (AMP002; NCT03243305). The study enrolled females of reproductive potential 18 to 35 years of age with regular menstrual cycles (21 to 35 days). The median age was 27.8 years. The racial distribution was 70.6% White, 23.7% Black or African American, 2.5% Asian, 0.4% American Indian or Alaska Native, 0.2% Native Hawaiian or Pacific Islander, and 2.7% other. Subjects agreed to engage in at least 3 acts of heterosexual, vaginal intercourse per cycle. Subjects self-administered a 5 gram dose of PHEXX intravaginally up to one hour before each episode of intercourse for up to 7 cycles.

The primary efficacy endpoint was the 7-cycle typical use cumulative pregnancy rate as derived by Kaplan-Meier life-table analysis. A total of 101 on-treatment pregnancies occurred in 1183 subjects contributing 4769 evaluable natural cycles. The 7-cycle cumulative pregnancy rate was 13.7% (95% CI: 10.0%, 17.5%), excluding cycles with back-up contraception, cycles <21 days or >35 days in length and cycles in which no intercourse was reported. The estimated Pearl Index, calculated based on data from the 7-cycle study, was 27.5 (95% CI: 22.4%, 33.5%).

16 HOW SUPPLIED/STORAGE AND HANDLING

PHEXX (lactic acid, citric acid, and potassium bitartrate) vaginal gel is an off-white to tan color gel of uniform consistency containing lactic acid (1.8%), citric acid (1%), and potassium bitartrate (0.4%), supplied as individually wrapped 5 gram pre-filled single-dose vaginal applicators in sealed foil pouches along with a plunger, and are available as follows:

- NDC 69751-101-12 Box of 12 units

Store in the original foil pack at room temperature 20°C to 25°C (68°F to 77°F); excursion permitted between 15°C to 30°C (59°F to 86°F) [*see USP Controlled Room Temperature*].

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the Patient Information and FDA-approved patient labeling (Instructions for Use). Advise the patient:

- To intravaginally administer the contents of one pre-filled single-dose applicator of PHEXX before **each** episode of vaginal intercourse and to administer an additional dose if intercourse does not occur within one hour of administration [*see Dosage and Administration (2.1)*].
- To consult their healthcare provider for severe or prolonged genital irritation [*see Adverse Reactions (6.1)]*.
- To discontinue PHEXX if they develop a local hypersensitivity reaction [*see Adverse Reactions (6.1)*].
- To contact their healthcare provider if experiencing urinary tract symptoms [*see Warnings and Precautions (5.1)*].
- That PHEXX does not protect against HIV infection and other sexually transmitted infections.

Manufactured for Evofem, Inc., a wholly owned subsidiary of Evofem Biosciences, Inc.
San Diego, CA 92130

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

What is PHEXX?
- PHEXX 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.
- PHEXX is not effective at preventing pregnancy when used **after** vaginal sex.

How well does PHEXX work?
Your chance of getting pregnant depends on how well you follow the directions for using PHEXX. 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.
PHEXX does not protect against HIV infection or other sexually transmitted infections (STIs).

Before using PHEXX, tell your healthcare provider about all of your medical conditions, including if you:
- are pregnant or think you are pregnant. PHEXX is not for use in pregnant women.
- are breastfeeding or plan to breastfeed. It is not known if PHEXX 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 PHEXX?
- See the **Instructions for Use** that come with PHEXX for detailed instructions on the right way to use PHEXX.
- Use PHEXX exactly as your healthcare provider tells you to use it.
- PHEXX must be used **before** vaginal sex.
- PHEXX comes as a pre-filled single-dose vaginal applicator.

- Insert 1 PHEXX pre-filled applicator into your vagina and use PHEXX **within 1 hour before each time** you have vaginal sex. If you do not have vaginal sex within 1 hour of using PHEXX, you must insert a new PHEXX pre-filled applicator.
- If you have vaginal sex more than 1 time within 1 hour, you must use a new PHEXX pre-filled applicator.
- PHEXX may be used at any time during the menstrual cycle.
- PHEXX 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.
- PHEXX may be used with hormonal contraceptives; and latex, polyurethane and polyisoprene condoms. PHEXX may be used with a vaginal diaphragm. Avoid using PHEXX with contraceptive vaginal rings.
- PHEXX 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 PHEXX?
PHEXX 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 PHEXX 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 PHEXX 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 PHEXX; **or** your sexual partners are allergic to any of the ingredients in PHEXX". Stop using PHEXX if you have a local vulvovaginal reaction.

The most common side effects of PHEXX include:

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

These are not all the possible side effects of PHEXX.
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 PHEXX?

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

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

General information about the safe and effective use of PHEXX.
Medicines are sometimes used for purposes other than those listed in a Patient Information leaflet. Do not use PHEXX for a condition for which it was not prescribed. Do not give PHEXX 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 PHEXX that is written for health professionals.

What are the ingredients in PHEXX?
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.phexx.com or call 1-833-EVFMBIO.
Manufactured for Evofem, Inc., a wholly owned subsidiary of Evofem Biosciences, Inc.

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

Issued: December 2024

INSTRUCTIONS FOR USE

PHEXX® (FEX)
(lactic acid, citric acid, and potassium bitartrate)
vaginal gel

For Vaginal Use Only

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

Contents:
- Each box contains 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 PHEXX for 1-time use (single use).

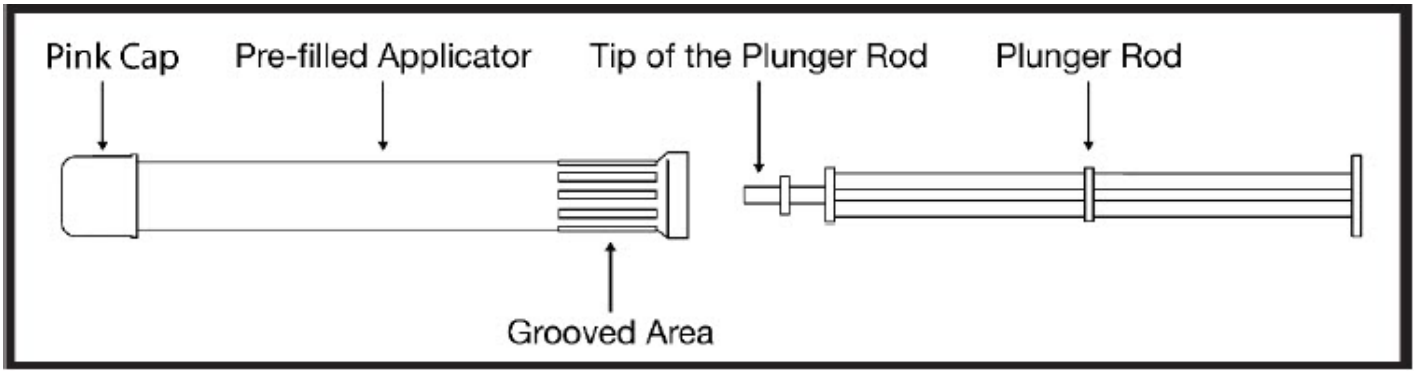


Figure A

Important Information You Need to Know Before Using PHEXX
- Use 1 dose of PHEXX **within 1 hour** before you have vaginal sex.
- A new PHEXX 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 PHEXX pre-filled applicator must be used**.

Prepare to Use PHEXX

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

PHEXX.

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).

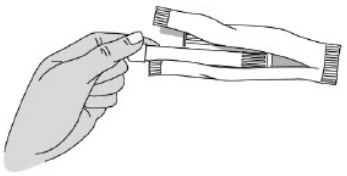


Figure B

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

Insert PHEXX 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.

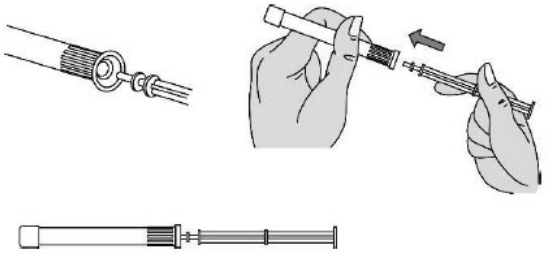


Figure C

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.

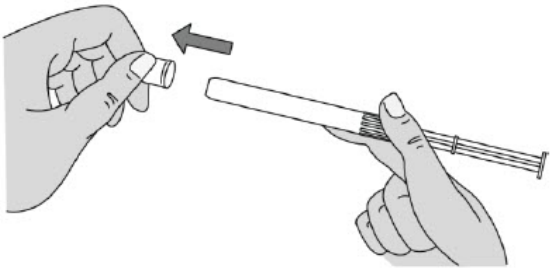


Figure D

Step 5: Insert the PHEXX Pre-filled Applicator into the Vagina

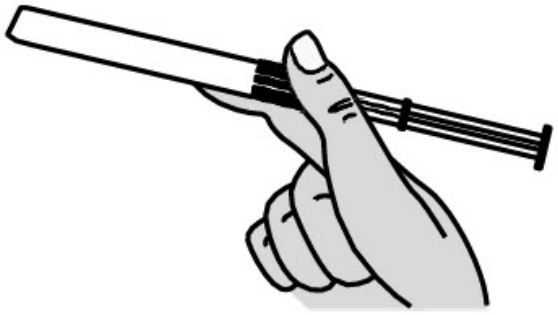


Figure E

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

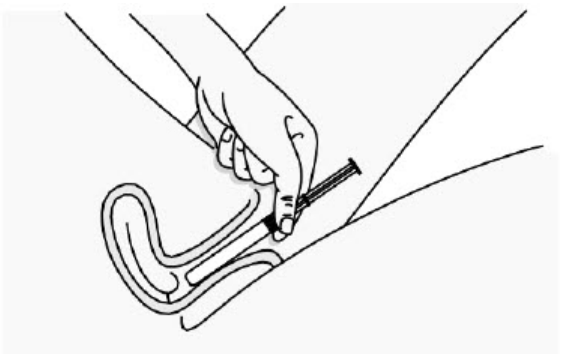


Figure F

Step 6: Insert PHEXX 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 PHEXX (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.

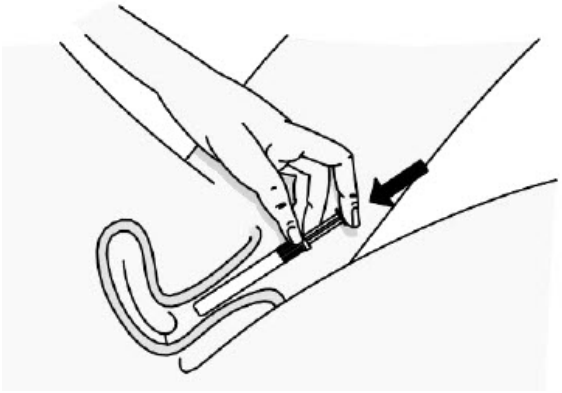


Figure G

Step 7: Remove the Used PHEXX 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.
- PHEXX 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 PHEXX gel and you still plan to have vaginal sex.

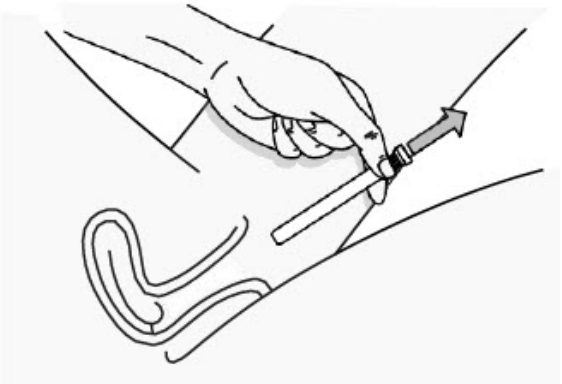


Figure H

Disposing of PHEXX

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

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

Storing PHEXX

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

Keep PHEXX 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.phexx.com or call 1-833-EVFMBIO.

Manufactured for Evofem, Inc., a wholly owned subsidiary of Evofem Biosciences, Inc.

Issued: December 2024

PRINCIPAL DISPLAY PANEL - 12 Applicator Box

phexx®

(lactic acid, citric acid, and
potassium bitartrate) Vaginal Gel
1.8%, 1%, 0.4%

NDC 69751-101-12
PN-XXXX RXX


phexx®
(lactic acid, citric acid, and potassium bitartrate) Vaginal Gel 1.8%, 1%, 0.4%
NDC 69751-101-12
PN-XXXX RXX
Active ingredients: lactic acid 1.8%, citric acid 1%, and potassium bitartrate 0.4%.
Each single-dose, pre-filled applicator contains: 5 g vaginal gel.
Store at 20°C-25°C (68°-77°F) with excursions permitted between 15°C-30°C (59°F-86°F) (see USP Controlled Room Temperature).
Use as directed by your healthcare provider.
See package insert for full Prescribing Information.
Phexxi does not protect against HIV infection (AIDS) and other sexually transmitted diseases.
Keep this and all medications out of reach of children.
Dispose of the applicator and the cap in the trash after use. Potential choking hazard.


phexx®
(lactic acid, citric acid, and potassium bitartrate) Vaginal Gel 1.8%, 1%, 0.4%
For Vaginal Use Only
Individually wrapped foils not to be sold separately.
Rx Only
Net Contents: 12 individually wrapped foil pouches; each containing one pre-filled, single-dose vaginal applicator and one plunger.

PHEXX

lactic acid, l-, citric acid monohydrate, and potassium bitartrate gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69751-101
Route of Administration	VAGINAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LACTIC ACID, L- (UNII: F9S9FFU82N) (LACTIC ACID, L- - UNII:F9S9FFU82N)	LACTIC ACID, L-	90 mg in 5 g
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	50 mg in 5 g
POTASSIUM BITARTRATE (UNII: NPT6P8P3UU) (TARTARIC ACID - UNII:W4888I119H)	POTASSIUM BITARTRATE	20 mg in 5 g

Product Characteristics			
Color	WHITE (off-white to tan)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
	NDC:69751			

1	NDC:69751-101-12	12 in 1 BOX	09/01/2020	
1	NDC:69751-101-01	5 g in 1 APPLICATOR; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA208352	08/01/2020	

Labeler - Evofem, Inc. (832466119)

Revised: 12/2024 Evofem, Inc.