Phexxi (lactic acid, citric acid, potassium bitartrate)

NEW PRODUCT SLIDESHOW

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Introduction

- **Brand name:** Phexxi
- **Generic name:** Lactic acid, citric acid, potassium bitartrate
- **Pharmacologic class:** Vaginal pH regulator
- **Strength and Formulation:** 1.8%, 1%, 0.4%; per 5 gram vaginal gel
- **Manufacturer:** Evofem Biosciences, Inc
- **How supplied:** Prefilled single-dose vaginal applicators—12
- **Legal Classification:** Rx

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Phexxi


For Vaginal Use Only
phexxi™
(lactic acid, citric acid, and potassium bitartrate) Vaginal Gel
1.8%, 1%, 0.4%
NDC 69751-100-12
PN-5011

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Indication

- Prevention of **pregnancy** in females of reproductive potential for use as an on-demand method of contraception.
  - *Limitations of use*: Not effective for the prevention of pregnancy when administered after intercourse.

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Dosage and Administration

- Insert 1 applicatorful vaginally immediately before or up to 1 hour before each act of vaginal intercourse.
- Must apply additional dose if more than 1 act of intercourse occurs within 1 hour.
- May use during any part of the menstrual cycle.
- May use as soon as it is safe to resume vaginal intercourse after childbirth, abortion, or miscarriage.
- May be used with hormonal contraceptives, condoms, vaginal diaphragms, other products for vaginal infections (eg, miconazole, metronidazole, tioconazole).

Considerations for Specific Populations

- **Pregnancy:** Discontinue during pregnancy; no data in pregnant women or animals.
- **Nursing mothers:** No data on the presence of Phexxi or its metabolites in human milk, effects on breastfed infant, or effects on milk production.
- **Pediatric**: Use before menarche is not indicated.

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Warnings and Precautions

- Avoid use in females of reproductive potential with a history of recurrent urinary tract infection or urinary tract abnormalities.

Interactions

- Avoid use with contraceptive vaginal rings.

Adverse Reactions

- **Most common (≥2%)**: Vulvovaginal effects (burning sensation, pruritus, mycotic infection, discomfort, pain), urinary tract infection, bacterial vaginosis, vaginal discharge, genital discomfort, dysuria.
- **Others**: Cystitis, pyelonephritis, hypersensitivity reaction.

Mechanism of Action

- *In vitro* studies showed that a pH-lowering effect and sperm motility reduction contribute to the activity of Phexxi in the vagina.

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Pharmacokinetics

- Systemic exposures of lactic acid, citric acid, and potassium bitartrate following vaginal administration of Phexxi are not expected to lead to safety concerns.

Clinical Trials

- Efficacy was evaluated in a multicenter, open-label, single-arm clinical trial (NCT03243305) that enrolled females of reproductive potential with regular menstrual cycles (21 to 35 days).
- Participants self-administered a 5 gram dose of Phexxi intravaginally up to 1 hour before each episode of intercourse for up to 7 cycles.
- The **primary efficacy end point** was the 7-cycle typical use cumulative pregnancy rate as derived by Kaplan-Meier life-table analysis.

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Clinical Trials

- **Patient demographics**
  - Median age: 27.8 years (range: 18 to 35 years).
  - 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; 2.7% other.
  - Patients agreed to engage in at least 3 acts of heterosexual, vaginal intercourse per cycle.

Clinical Trials

- Results showed a total of 101 on-treatment pregnancies occurred in 1183 participants contributing 4769 evaluable natural cycles.
- The 7-cycle cumulative pregnancy rate was 13.7% (95% CI, 10-17.5), 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-cyce study, was 27.5 (95% CI, 22.4-33.5).

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New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/drug/phexxi/