

# STEPS

## New Drug Reviews

### Lactic Acid, Citric Acid, and Potassium Bitartrate (Phexxi) Vaginal Gel for Contraception

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Drug	Starting dose	Dose form	Cost*
Lactic acid, citric acid, and potassium bitartrate (Phexxi)	Insert 5 g vaginally immediately before or up to one hour before sexual intercourse	Vaginal gel: lactic acid 1.8%, citric acid 1%, potassium bitartrate 0.4%	\$285

\*—Estimated lowest GoodRx price for one box of 12 prefilled applicators based on information obtained at <http://www.goodrx.com> (accessed March 31, 2021; zip code: 66211).

Lactic acid, citric acid, and potassium bitartrate (Phexxi) is a vaginal gel labeled for use by women as an on-demand contraception. The gel maintains vaginal pH at its physiologic acidity, creating an environment inhospitable to sperm that inhibits sperm motility.

#### Safety

Phexxi is considered to be a safe contraceptive option. In two trials of 4,773 women, approximately 1% of patients experienced adverse effects, but none of the effects were shown to be caused by Phexxi.<sup>1,2</sup> Systemic exposure to the active ingredients in the gel is minimal and is not expected to lead to safety concerns. Phexxi is not absorbed and will not cause systemic effects.<sup>3</sup>

**STEPS new** drug reviews cover Safety, Tolerability, Effectiveness, Price, and Simplicity. Each independent review is provided by authors who have no financial association with the drug manufacturer.

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The manufacturer recommends that Phexxi be avoided in patients with a history of recurrent urinary tract infections or urinary tract abnormalities. The water-based gel does not interact with other vaginal products like miconazole, metronidazole (Metrogel), and tioconazole.<sup>3</sup> Phexxi is safe to use in conjunction with hormonal contraceptives, latex, polyurethane, polyisoprene condoms, and vaginal diaphragms. It should not be used with vaginal rings.<sup>3</sup> Phexxi can be used after childbirth as soon as it is safe to resume vaginal intercourse.

#### Tolerability

The most common adverse effects of Phexxi are localized to the vagina and include burning sensation (18%), itching (14.5%), vulvovaginal mycotic infection (9.1%), urinary tract infection (9%), bacterial vaginosis (8.1%), and vaginal discharge (5.5%).<sup>3</sup> More than 45% of study participants experienced at least one adverse effect, but the majority were deemed mild to moderate in severity, and only 2% to 3% of study participants dropped out because of adverse effects.<sup>1,2</sup> These rates and types of adverse effects are similar to those that occur with nonoxynol-9, the ingredient in over-the-counter spermicidal products.<sup>2</sup> Male partners may also experience mild reactions such as itching, burning, and pain (9.8%).<sup>3</sup>

## Effectiveness

Two studies have evaluated contraceptive effectiveness over an average of six months of use. In a case series of 1,330 women 18 to 35 years of age, 13.7% of women became pregnant during six months of use.<sup>1</sup> In an unpublished randomized controlled trial of 3,324 women 18 to 35 years of age comparing Phexxi with the spermicide nonoxynol-9, Phexxi demonstrated an 89.5% pregnancy prevention rate with typical use and 95.9% with ideal use over six months, similar to the rates with nonoxynol-9 (90.0% and 95.8%, respectively).<sup>2</sup> Although there are no data regarding 12-month effectiveness of Phexxi, the six-month typical-use rates would likely be comparable to other on-demand methods such as condoms (87% pregnancy prevention rate with typical use over 12 months). However, pregnancy prevention rates with Phexxi are lower than with oral contraceptives (92%) and intrauterine devices or progestin implants (greater than 99%).<sup>4</sup> Table 1 compares first-year pregnancy prevention rates of various contraceptive methods with typical and ideal use.<sup>2,4</sup>

## Price

One box of 12 prefilled applicators of Phexxi costs about \$285, or approximately \$24 for on-demand contraception per act of intercourse. One box of 10 prefilled applicators of spermicide nonoxynol-9 is \$11, or about \$1 per act of intercourse.<sup>5</sup> Condoms, often available free of charge at many civic and family planning organizations, offer on-demand contraception for \$0.25 to \$0.50 per act of intercourse.

## Simplicity

A prefilled applicator of Phexxi (5 g) must be inserted into the vagina immediately before or up to one hour before each act of vaginal intercourse. An additional 5-g dose must be used if more than one act of vaginal intercourse occurs within one hour. Phexxi can be stored at room temperature.

## Bottom Line

Given its high cost, mediocre contraceptive protection, and rate of adverse effects, Phexxi may be preferred only by people desiring to avoid hor-

TABLE 1

### First-Year Pregnancy Prevention Rates of Various Contraceptive Methods

Method	Typical use	Ideal use
Progestin implant (12-month data)	99.9%	99.9%
Progestin intrauterine device (12-month data)	99.8%	99.8%
Combined oral contraceptives (12-month data)	92%	99.7%
Male condom (12-month data)	87%	98%
Withdrawal (12-month data)	80%	96%
Nonoxynol-9 spermicide (12-month data)	79%	84%
Phexxi (six-month data)	86% to 89%	96%

Information from references 2 and 4.

monal contraception who wish to use on-demand contraception that they control, or for whom other contraceptive options are not suited or desired.

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