

Phexxi™ (lactic acid/citric acid/potassium bitartrate) – New drug approval

- On May 22, 2020, [Evoform announced](#) the FDA approval of [Phexxi \(lactic acid/citric acid/potassium bitartrate\)](#), for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.
 - Phexxi is not effective for the prevention of pregnancy when administered after intercourse.
- Phexxi is the first non-hormonal, on-demand, vaginal pH regulator contraceptive. *In vitro* studies showed that a pH lowering effect and sperm motility reduction contribute to the activity of Phexxi in the vagina.
- The efficacy of Phexxi for the prevention of pregnancy was evaluated in an open-label, single-arm study. Patients agreed to engage in at least 3 acts of heterosexual, vaginal intercourse per cycle. Patients self-administered Phexxi 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. A total of 101 on-treatment pregnancies occurred in 1183 patients 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.
- A warning and precaution for Phexxi is cystitis and pyelonephritis.
- The most common adverse reactions (≥ 2%) with Phexxi use were vulvovaginal burning sensation, vulvovaginal pruritus, vulvovaginal mycotic infection, urinary tract infection, vulvovaginal discomfort, bacterial vaginosis, vaginal discharge, genital discomfort, dysuria, and vulvovaginal pain.
- The recommended dosage of Phexxi is one pre-filled applicator (5 grams) administered 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.
 - Phexxi may be used during any part of the menstrual cycle and as soon as it is safe to resume vaginal intercourse after childbirth, abortion, or miscarriage.
 - Phexxi may be used concomitantly with hormonal contraceptives; latex, polyurethane, and polyisoprene condoms; and vaginal diaphragms. Phexxi use with vaginal rings should be avoided.
- Evoform plans to launch Phexxi in early September 2020. Phexxi will be available as 5 gram pre-filled single-dose vaginal applicators.
 - Five grams of Phexxi contains 90 mg of lactic acid, 50 mg of citric acid, and 20 mg of potassium bitartrate.