

Developed to Maintain a Proper Vaginal pH Level

fem pH can be used to promote or maintain vaginal acidity due to these and other factors:

- Diabetes
- Lifestyle
- Compromised Immune System
- Hormonal Changes
- Antibiotics
- Steroids





fem pH™ - Therapeutic Vaginal Jelly

DESCRIPTION: *fem pH* Vaginal Jelly is a bland, non-irritating water dispersible, buffered acid jelly for intravaginal use. *fem pH* is classified as a Vaginal Therapeutic Jelly. *fem pH* contains 0.9% glacial acetic acid (C2H4O2) and 0.025% oxyquinoline sulfate (C18H16N2O6S) compounded with glycerin, lactic acid, polyethylene glycol 4600 and purified water. *fem pH* is formulated to pH 3.8–4.3 and is adjusted using 1N potassium hydroxide.

CLINICAL PHARMACOLOGY: *fem pH* acts to restore and maintain normal vaginal acidity through its buffered action.

INDICATIONS AND USAGE: *fem pH* is indicated as adjunctive therapy in those cases where restoration and maintenance of vaginal acidity is desirable.

CONTRAINDICATIONS: None known.

WARNINGS: No serious adverse reactions or potential safety hazards have been reported with the use of *fem pH*.

PRECAUTIONS:

General: No special care is required for the safe and effective use of *fem pH*.

Drug Interactions: No incidence of drug interactions has been reported with concomitant use of *fem pH* and any other medication.

Laboratory Tests: The monitoring of vaginal acidity (pH) may be helpful in following the patient's response. (The normal vaginal pH has been shown to be in the range of 4.0 to 5.0)

Carcinogenesis: No long-term studies in animals have been performed to evaluate carcinogenic potential.

Pregnancy: Pregnancy Category C. Animal reproduction studies have not been conducted with *fem pH*. It is not known whether *fem pH* can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. *fem pH* should be given to a pregnant woman only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when *fem pH* is administered to a nursing woman.

ADVERSE REACTIONS: Occasional cases of local stinging and burning have been reported.

DOSAGE AND ADMINISTRATION: The usual dose is one applicator full, administered intra-vaginally, morning and evening. Duration of treatment may be determined by the patient's response to therapy. Replace cap after each use. To fill applicator screw applicator clockwise onto the tube. Squeeze tube forcing *fem pH* jelly into barrel until it is full. Then unscrew applicator counterclockwise to remove from tube. Lie on your back with knees drawn up. Hold filled applicator by the barrel and gently insert it into the vagina as far as it will comfortably go. Press plunger to empty the contents. Keep the plunger depressed and remove the applicator from vagina. After each use pull applicator apart and wash with warm soapy water, rinse well, dry and reassemble.

HOW SUPPLIED: 50g Tube (NDC 00813-0799-55) with *fem pH* applicator.

Keep this and all medication out of the reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

Store at controlled room temperature 59 - 86 F (15 - 30 C)



fem pH

Sig: One applicator full B.I.D. Disp: 50 grams with applicator

Refill: PRN

Manufactured By:

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