FEM PH- acetic acid and oxyquinoline sulfate jelly
Pharmics, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Fem pH™

Therapeutic Vaginal Jelly

Rx Only

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 (C2H402) and 0.025% oxyquinoline sulfate (C18H16N206S) compounded with glycerin, lactic acid, poly ethylene glycol 4500 and purified water. ***Fem pH*** is formulated to pH 3.8-4.3 and is adjusted using 1 N 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 hazard 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. Each tube has a tamper evident seal at the opening of the tube. 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 counter-clockwise 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)

Mfg. by:
Pernix Manufacturing
Houston, TX 77099

Mfg. for:
Pharmics, Inc.
Salt Lake City, UT 84119
(801) 966-4138
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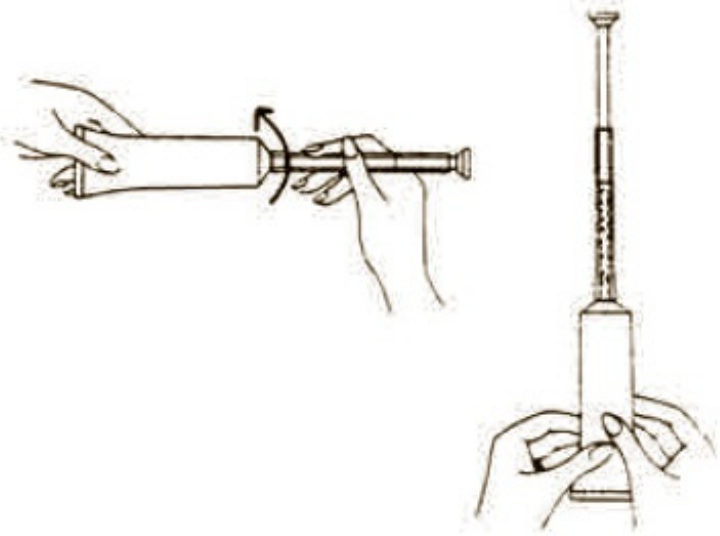
Revised 05/13

Therapeutic Vaginal Jelly

Directions for using Fem pH applicator.



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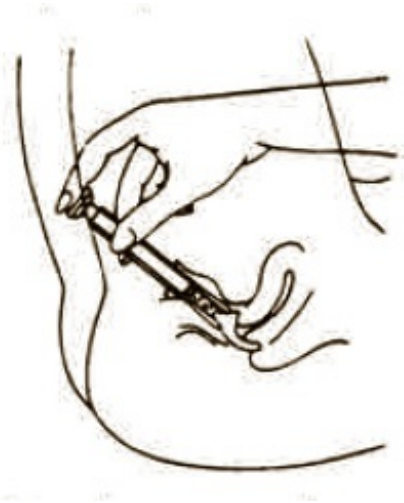

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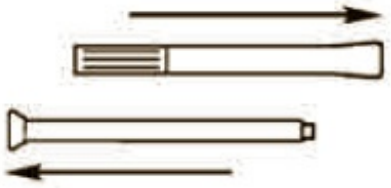


PRINCIPAL DISPLAY PANEL - 50g Tube Box

NDC 00813-0799-55

Rx Only

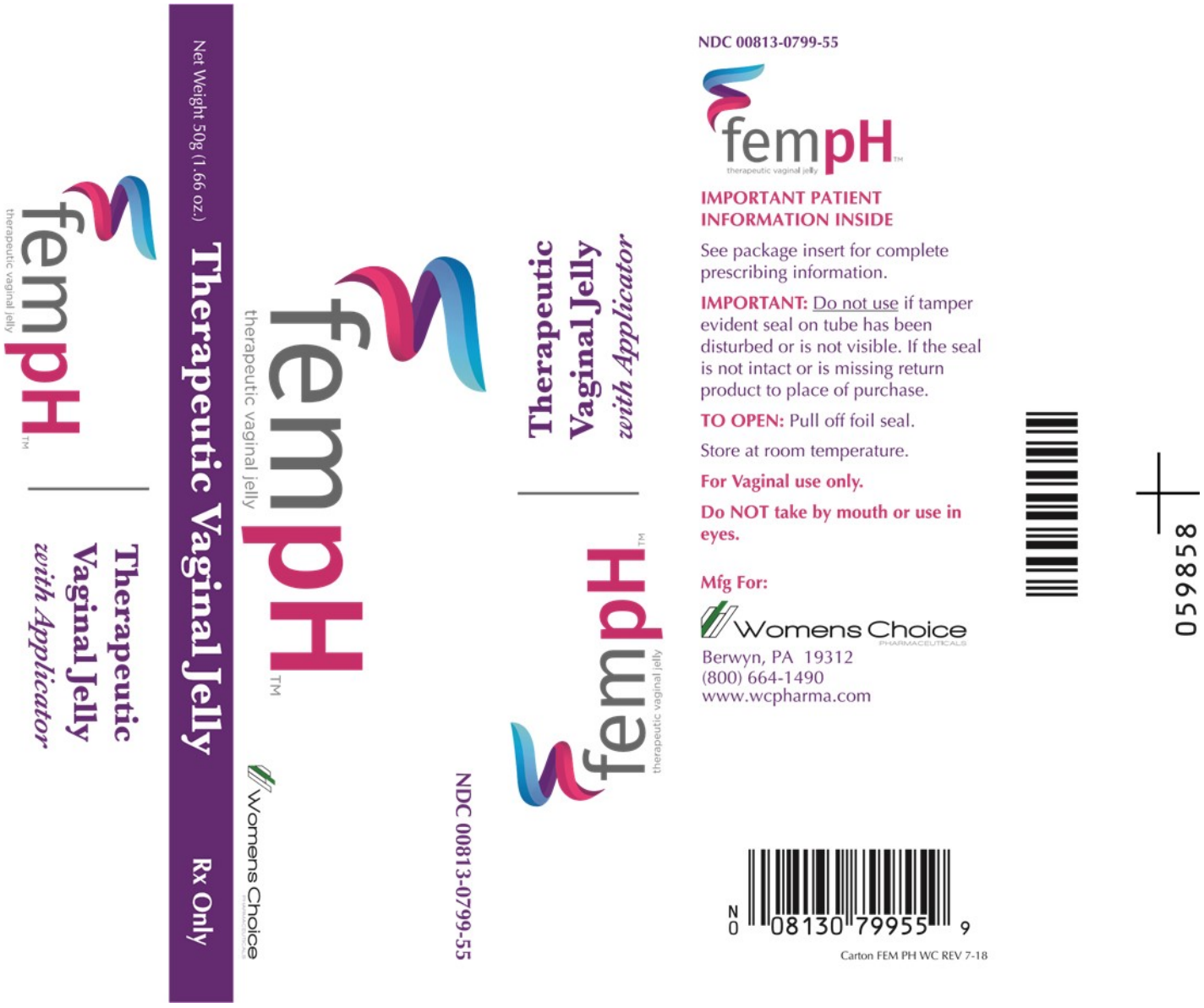
Fem pH™

Therapeutic Vaginal Jelly

Net Weight 50g

(1.66 oz.)

pharmics INC



FEM PH

acetic acid and oxyquinoline sulfate jelly

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0813-0799
Route of Administration	VAGINAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

ACETIC ACID (UNII: Q40Q9N063P) (ACETIC ACID - UNII:Q40Q9N063P)	ACETIC ACID	0.009 g in 1 g
OXYQUINOLINE SULFATE (UNII: 61VUG75Y3P) (OXYQUINOLINE - UNII:5UTX5635HP)	OXYQUINOLINE	0.00025 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID (UNII: 33X04XA5AT)	
POLYETHYLENE GLYCOL 4500 (UNII: TVH7653921)	
WATER (UNII: 059QF0KO0R)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0813-0799-55	50 g in 1 TUBE; Type 0: Not a Combination Product	07/15/1999	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/15/1999	

Labeler - Pharmics, Inc. (058560996)

Revised: 11/2018 Pharmics, Inc.