

CTD MODULE 1
ADMINISTRATIVE INFORMATION AND
PRODUCT INFORMATION

Product Name :	MYCOREN V PESSARIES (Nystatin Pessaries 100,000 IU)
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Pack Insert:

MYCOREN – V PESSARIES

COMPOSITION

Nystatin BP 100,000 IU

PHARMACEUTICAL FORM: Pessaries

CLINICAL PARTICULARS

Therapeutic Indications

For the treatment of candidal vaginitis.

POSOLGY AND METHOD OF ADMINISTRATION PESSARIES:

DOSAGE

Adults including the elderly:

1 or 2 pessaries should be inserted high into the vagina for 14 consecutive nights or longer, regardless of any intervening menstrual period.

Children: Not recommended.

Route of administration: Vagina

USAGE OF APPLICATOR

Thoroughly wash the applicator with warm water and dry prior to use. Place the vaginal tablet in the holder of applicator, insert the applicator in the vagina in such a way that the tablet reaches in depth up to the cervix. Push the plunger to eject the tablet.

CONTRAINDICATIONS

There are no known contraindications to use of Mycoren V Pessaries, except

Hypersensitivity to any of the ingredients.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

In pregnancy, care should be taken when using an applicator to prevent the possibility of mechanical trauma.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Not known.

PREGNANCY AND LACTATION: In pregnancy, care should be taken when using the applicator provided to prevent the possibility of mechanical trauma.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES: None.

UNDESIRABLE EFFECTS: None stated.

OVERDOSE: None.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Nystatin exerts its effect by interaction with cell walls and cell membranes. Sterols present in the cell membrane are necessary for this effect. Nystatin has both fungistatic and fungicidal effects.

PHARMACOKINETIC PROPERTIES

Nystatin is an antifungal antibiotic active against *Candida albicans* and a wide range of yeast-like fungi.

PRECLINICAL SAFETY DATA: Not applicable

INCOMPATIBILITIES: None known.

SHELF LIFE: 24 months.

SPECIAL PRECAUTIONS FOR STORAGE

Store in a dry and dark place, between 15° C-30°C.

Keep out of reach of children. Do not swallow.

PACK SIZE: Blister Pack of 1x15 Pessaries with applicator.

Jar 100 Pessaries

SPECIAL PRECAUTIONS FOR DISPOSAL

No special precautions. Use as directed by the physician.

MANUFACTURED BY
RENE INDUSTRIES LTD.

Plot 680 Kamuli, Kireka
P. O. Box 6034 KAMPALA - UGANDA



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