

Data Sheet

Resolve Thrush Vaginal Cream 2 %

Miconazole nitrate

Presentation

A glossy, firm thick cream containing 2%w/w miconazole nitrate. Water miscible, pH 2.3 to 4.8.

Uses

Actions

Miconazole nitrate is a synthetic 1-phenethylimidazole derivative. Miconazole nitrate exhibits *in-vitro* activity against species of the genus *Candida*. *In-vitro* fungicidal activity has been demonstrated particularly against *Candida albicans*.

Pharmacokinetics

Miconazole nitrate is not significantly absorbed when administered intravaginally.

Indications

Resolve Thrush Vaginal Cream 2 % is indicated for the treatment vulvovaginitis due to *Candida albicans* and other *Candida* species.

Dosage and Administration

Insert one applicator full of cream (5g), intravaginally once daily (at bedtime) for seven days.

Contraindications

Known sensitivity to miconazole nitrate or any of the other ingredients in the preparation.

Warnings and Precautions

Discontinue use if sensitisation or irritation occurs.

Resolve Thrush Vaginal Cream 2 % is only effective against vulvovaginitis due to *Candida* species. Other pathogens commonly associated with vulvovaginitis (*Trichomonas* and *Haemophilus vaginitis*) should be ruled out by the appropriate laboratory/diagnostic methods.

During treatment it is recommended that the patient refrains from sexual intercourse, or that the male partner wears a condom.

Use in Pregnancy: Miconazole has not shown embryotoxic or teratogenic effects in animals. The safety for use during pregnancy in humans has not been established. Since miconazole is absorbed in very small amounts from 2% vaginal cream preparations, FUNGO Cream should only be used in the first trimester of pregnancy when the physician considers it to be essential to the patient.

Caution should be exercised with the insertion of the applicator during pregnancy.

Adverse Effects

Miconazole nitrate vaginal preparations are generally well tolerated with few adverse effects. Adverse effects include vulvovaginal irritation, itching or burning (6%), other complaints occur very rarely (<0.2%) these include vaginal burning, pelvic cramps, hives, skin rash and headaches.

Interactions

Nil.

Overdosage

No reports have yet appeared concerning overdose after oral miconazole administration. The topical absorption of miconazole nitrate through the skin is not significant.

Pharmaceutical Precautions

Store below 30°C Keep out of reach of children.

Medicine Classification

Restricted Medicine

Package Quantities

Resolve Thrush Vaginal Cream 2 % 40g, with 5g applicator.

Further Information

FUNGO contains miconazole nitrate the chemical name for which is 1-[2,4-dichloro- β -(2,4-dichlorobenzyloxy) phenethyl] imidazole nitrate. Miconazole nitrate has a molecular weight and formula of 479.1 and $C_{18}H_{14}Cl_4N_2O.HNO_3$, respectively.

Other ingredients of the cream are: butylene glycol, cetostearyl alcohol, dimethicone, glycerol monostearate, light liquid paraffin, polyoxyl-40-stearate and phenethyl alcohol as a preservative.

Name and Address

Resolve Thrush Vaginal Cream 2 % is distributed in New Zealand by:

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Date of Preparation

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