

# **MICOZOLE**

## **Miconazole nitrate vaginal cream USP, 2%**

### **Presentation**

MICOZOLE Vaginal Cream 2% contains the synthetic bactericidal and fungicidal broad spectrum antifungal agent miconazole nitrate in cream. Also contains apricot kernel oil, benzoic acid, BHA, glycol stearate, mineral oil, PEG-6, PEG-6-32 stearate, and purified water.

### **Uses**

#### ***Actions***

Miconazole combines a potent antifungal activity against common dermatophytes and yeasts with an antibacterial activity against certain Gram-positive bacilli and cocci. Miconazole inhibits the biosynthesis of ergosterol in fungi and changes the composition of other lipid components in the membrane, resulting in fungal cell necrosis.

#### ***Pharmacokinetics***

Systemic absorption after intravaginal administration is limited. Eight hours after application 90% of miconazole nitrate is still present in the vagina. Unchanged miconazole could not be traced in blood plasma or urine.

#### ***Indications***

Local treatment of vulvovaginal candidiasis and superinfections due to Gram-positive bacteria. MICOZOLE Vaginal Cream may also be used for treatment of mycotic balanitis.

### **Dosage and Administration**

Once daily (before bedtime) the contents of one applicatorful of cream (approximately 5g) should be squeezed deeply into the vagina, for seven days, even after pruritis and leukorrhoea has disappeared.

For relief of external vulvar itching a small amount of cream should be squeezed onto the finger and applied gently to the irritated area of the vulva once to twice daily. The pack (45g) has extra cream to allow for this external local treatment.

### **Contraindications**

MICOZOLE Vaginal Cream is contraindicated in individuals who have shown hypersensitivity to miconazole or any other components of the medicine.

## **Warnings and Precautions**

Should local sensitisation or an allergic reaction occur, the treatment should be discontinued.

General hygienic measures should be observed to control sources of infection and re-infection.

Appropriate therapy is also indicated when the sexual partner is also infected.

### ***Use during pregnancy and lactation:***

Although intravaginal absorption is limited, MICOZOLE Vaginal Cream should only be used in the first trimester of pregnancy if, in the judgement of the physician, the potential benefits outweigh the risks.

It is not known whether miconazole nitrate is excreted in human milk. Caution should be exercised when using miconazole nitrate during lactation.

## **Adverse Effects**

MICOZOLE Vaginal Cream is usually well tolerated.

A few cases of local irritation, pruritis and burning sensations have been observed, especially at the start of treatment.

## **Interactions**

Contact should be avoided between certain latex products such as contraceptive diaphragms or condoms and MICOZOLE Vaginal Cream since the rubber may be damaged, leading to unintended pregnancy or transmission of infectious disease.

An interaction between miconazole and cisapride resulting in prolongation of the QT interval and cardiac arrhythmias has been reported. This combination should be avoided.

## **Overdosage**

In the event of accidental ingestion of large quantities of MICOZOLE Vaginal Cream, an appropriate method of gastric emptying such as emesis induced by syrup of ipecac may be used if considered appropriate.

## **Pharmaceutical Precautions**

Shelf life is 2 years. Store below 30 degrees celsius.

## **Medicine Classification**

Pharmacist Only Medicine.

## **Package Quantities**

45g pack with 5g vaginal applicator.

## **Further Information**

Nil.

## **Name and Address of Supplier**

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## **Date of Preparation**

8 December 1997