

MICREME

Miconazole Nitrate 2%w/w Vaginal Cream



Presentation

MICREME vaginal cream (2%w/w) is a smooth white cream which contains the synthetic bactericidal and fungicidal broad-spectrum antifungal agent miconazole nitrate.

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.

In general, miconazole exerts a very rapid effect on pruritus, a symptom that frequently accompanies dermatophyte and yeast infections.

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.

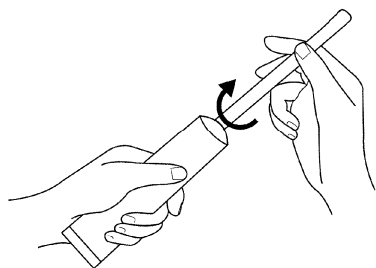
MICREME may also be use for the treatment of mycotic balanitis.

Dosage and Administration

MICREME should be used once daily (before bedtime), the contents of one applicator (approximately 5g of cream) should be squeezed deeply into the vagina, for seven days, even after pruritus and leukorrhoea has disappeared.

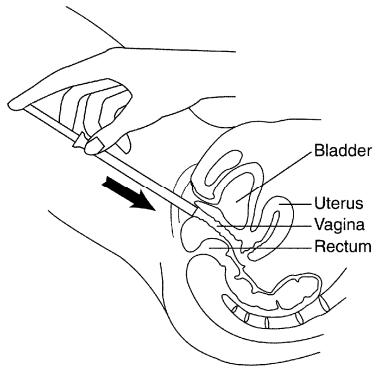
Patient Instructions for Use

A) Filling the Applicator



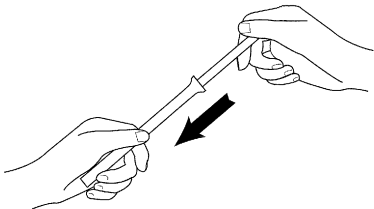
1. Wash your hands thoroughly.
2. Remove the cap from the tube, and use the reverse side of the cap to pierce the tube nozzle.
3. Screw the applicator to the tube, and fill the applicator by squeezing the bottom of the tube until the plunger is fully extended.
4. Unscrew the applicator from the tube and replace the tube cap.

B) Inserting the Applicator



1. Hold the filled applicator by the cylinder and carefully insert into the vagina, as far as is comfortably possible. This is best achieved by lying on your back with your knees bent.
2. Slowly press the plunger until it stops. This places the cream into the vagina.
3. Remove the applicator from the vagina with plunger still depressed.

C) Care of the Applicator



After each use, wash the applicator thoroughly. It can be taken apart by firmly pushing the head of the plunger up inside the cylinder. Withdraw the plunger from the cylinder. Wash the parts in warm water, with a mild detergent, and rinse thoroughly. Reassemble by pushing the plunger into the cylinder.

Contraindications

MICREME is contraindicated in individuals who have shown hypersensitivity to miconazole or any other components of these medicines.

Warnings and Precautions

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

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

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

Pregnancy and Lactation

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

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

Adverse Effects

MICREME is usually well tolerated, and adverse reactions are rare and mild in most cases.

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

Interactions

MICREME vaginal cream should not be used in combination with rubber products – such as condoms and diaphragms, as MICREME may destroy the rubber. It is therefore recommended that condoms, diaphragms and spermicides should not be used in combination with MICREME, as these forms of contraception may fail in which case pregnancy or sexually transmitted disease cannot be prevented.

Overdosage

In the event of accidental ingestion of large quantities of this medicine, an appropriate method of gastric emptying may be used if considered appropriate.

Pharmaceutical Precautions

Store below 25°C.

Medicine Classification

Restricted Medicine.

Package Quantities

MICREME Vaginal Cream 40g with 5g applicator.

Further Information

Nil.

Name and Address

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