Miconazole 2% Vaginal Cream

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QUALITATIVE AND QUANTITATIVE COMPOSITION
Miconazole nitrate 2% w/w.

PHARMACEUTICAL FORM
Vaginal cream.

Therapeutic indications
For the treatment of mycotic vulvovaginitis and superinfections due to gram-positive bacteria.

Dosage and method of administration
Miconazole vaginal cream is for vaginal administration. The cream should be applied around the vaginal introitus and onto the vaginal wall. A single applicator delivers approximately 5 g of cream. One applicator should be used once daily for 7 days or twice daily for 4 days. For vulvitis, the cream should be applied topically twice daily. Continue the course of treatment even after pruritus and leukorrhoea have disappeared or menstruation begins.

Contraindications
Miconazole vaginal cream is contraindicated in individuals with a known hypersensitivity to miconazole or another ingredient of the cream. Miconazole vaginal cream is contraindicated in a known hypersensitivity to miconazole or another ingredient of the cream.

Special warnings and precautions for use
Miconazole vaginal cream does not stain skin or clothes. The concurrent use of latex condoms or diaphragms with vaginal anti-infective preparations may decrease the effectiveness of latex contraceptive agents. Therefore, Miconazole vaginal cream should not be used concurrently with a latex condom or latex diaphragm.

Interaction with other medicinal products and other forms of interaction
Miconazole administered systemically is known to inhibit CYP3A4/2C9. Due to the limited systemic availability after vaginal application, clinically relevant interactions occur very rarely. In patients on oral anticoagulants, such as warfarin, caution should be exercised and anticoagulant effect should be monitored. The effects and side effects of other drugs metabolized by CYP2C9 (e.g., oral hypoglycemics and phenytoin) and also CYP3A4 (e.g., HMG-CoA reductase inhibitors such as simvastatin and lovastatin and calcium channel blockers such as diltiazem and verapamil), when co-administered with miconazole, can be increased and caution should be exercised.

Contact should be avoided between certain latex products such as contraceptive diaphragms or condoms and Miconazole vaginal cream since the constituents of the cream may damage the latex.

Pregnancy
Although intravaginal absorption is limited, Miconazole vaginal cream should only be used in the first trimester of pregnancy only if, in the judgment of the physician, the potential benefits outweigh the possible risks.

Lactation
It is not known whether Miconazole nitrate is excreted in human milk. Caution should be exercised when using Miconazole vaginal cream during lactation.

Effects on ability to drive and use machines
None known.

Undesirable effects
The safety of was evaluated in a total of 537 women with microbiologically confirmed candidiasis and symptoms (e.g., vulvovaginal itching, burning/irritation), or signs of vulvar erythema, edema, excoriation, or vaginal erythema or edema who participated in 2 single-blind clinical trials. Subjects were treated with miconazole intravaginally, randomly assigned to either a single 1,200 mg capsule, or a 7-day application of 2% vaginal cream. Adverse Drug Reactions (ADRs) reported by % of Miconazole vaginal-treated subjects in these trials are shown in Table 1.

Adverse Drug Reactions Reported by Miconazole vaginal-treated Subjects in 2 Single Blind Clinical Trials

Skin and subcutaneous tissue disorders
Common Rash
Uncommon Rash pruritic, urticaria

Reproductive System and Breast Disorders
Very common Genital pruritus female, vaginal burning sensation, vulvovaginal discomfort
Common Dysmenorrhoea

A range of additional reactions were reported during the clinical trials, such as: vaginal discharge, vaginal haemorrhage, vaginal pain, headache, dysuria, urinary tract infection, abdominal pain, rosacea, swelling face and nausea. However due to the design of these studies, a definitive causal relationship could not be established.

Overdose
Symptoms
In case of accidental ingestion, no problems are expected.

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

Special precautions for storage
Do not store above 25ºC.

Special precautions for disposal and other handling
No special requirements.