

NEW ZEALAND DATA SHEET

MICREME H

Topical cream

Miconazole nitrate 2%; hydrocortisone 1%



Presentation

A smooth, white cream containing miconazole nitrate 2% and hydrocortisone 1%.

Uses

Actions

Miconazole has antifungal activity against the common dermatophytes, yeasts and various other fungi as well as 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.

Miconazole has also proven to be effective in secondarily infected mycoses.

Hydrocortisone is a natural corticosteroid with a potent anti-inflammatory and anti-pruritic action.

MICREME H combines the broad spectrum anti-fungal and antibacterial activity of miconazole with the anti-inflammatory and antipruritic action of hydrocortisone. It acts very rapidly on pruritus, which frequently accompanies dermatophyte and yeast infections. Symptomatic improvement is seen before the first signs of healing are observed. However, treatment is symptomatic and pruritus may flare up again after discontinuation of steroid treatment.

Pharmacokinetics

Miconazole does not produce detectable blood levels after topical application.

Depending on the location and type of infection, hydrocortisone penetrates well into the skin and is partially absorbed. More than 90% of the absorbed fraction is bound to plasma proteins. The metabolism takes place in the liver and tissues and the metabolites are excreted with the urine, mostly as glucuronides, together with a very small fraction of unchanged hydrocortisone. The biological half-life is about 100 minutes.

Indications

MICREME H is indicated for the treatment of skin infections caused by yeast, dermatophytes or gram-positive bacteria, in which inflammatory symptoms are predominant. MICREME H may also be used for mycotic infections with bacterial superinfection.

Dosage and Administration

MICREME H should be applied topically to the lesion once to twice daily. Squeeze 1 cm of cream (or more, according to the size of the lesion) onto the lesion and rub in gently until the cream has been completely absorbed by the skin. The treatment with MICREME H (or subsequently with MICREME) should be continued without interruption until the lesion has completely disappeared (usually after 2 to 5 weeks). MICREME H is particularly indicated for the initial stages of treatment.

Discontinue MICREME H cream on disappearance of the inflammatory symptoms (or after a maximum treatment period of 2 weeks) and continue treatment with an antifungal cream only until complete disappearance of the lesion (usually 2 to 5 weeks).

Contraindications

Hypersensitivity to any of the ingredients, viral disease of the skin (herpes, chickenpox), perioral dermatitis, rosacea, ulcerative conditions, tuberculous or syphilitic processes.

Warnings and Precautions

If a reaction suggesting sensitivity or irritation does occur, the treatment should be discontinued. MICREME H must not come into contact with the mucosa of the eyes.

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

As with any topical corticosteroid, care is advised with infants and children when MICREME H is to be applied to extensive surface areas or under occlusive dressings, including baby napkins. Similarly, application to the face should be avoided.

In infants, long term continuous topical corticosteroid therapy should be avoided. Adrenal suppression can occur even without occlusion.

MICREME H can damage certain synthetic materials. Therefore, it is recommended that cotton underwear be worn where clothing contacts the affected area.

Pregnancy and Lactation

Caution is recommended during pregnancy and lactation. Treatment of large surfaces and the application under occlusive dressing should be avoided during that time.

Adverse Effects

MICREME H is generally well tolerated.

There have been isolated reports of irritation or burning sensation associated with the application of MICREME H.

As with all substances applied to the skin, an allergic reaction to any of the ingredient of the cream may occur.

Interactions

None known.

Overdosage

Symptoms

Prolonged and excessive use can result in skin irritation, which usually disappears after discontinuation of therapy. Topically applied, corticosteroids can be absorbed in sufficient amounts to produce systemic effects.

Treatment

If accidental ingestion of large quantities of the product occurs, an appropriate method of gastric emptying may be used if considered to be necessary.

Pharmaceutical Precautions

Store below 25°C.

Medicine Classification

Pharmacist Only Medicine.

Package Quantities

15 gram tube.

Further Information

A broad spectrum antifungal, gram positive antibacterial and an anti-inflammatory agent gives a combination that can be used in a wide variety of skin conditions from bacterially superinfected fungal lesions through to inflammatory lesions with fungal overgrowth.

Name and Address

Mylan New Zealand Ltd
PO Box 11-183
Ellerslie
AUCKLAND
Telephone: 09-579-2792

Date of Preparation

2 February 2009