

DATA SHEET

NAME OF MEDICINE

DAKTACORT™

miconazole nitrate 2% and hydrocortisone 1% cream

PRESENTATION

A white, homogenous, odourless 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 been proven to be effective in secondarily infected mycoses.

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

DAKTACORT combines the broad spectrum antifungal and antibacterial activity of miconazole with the anti-inflammatory and antipruritic action of hydrocortisone. It acts very rapidly on pruritis, which frequently accompanies dermatophyte and yeast infections. Symptomatic improvement is seen before the first signs of healing are observed. However, treatment is symptomatic and pruritis 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

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

DOSAGE AND ADMINISTRATION

DAKTACORT should be applied topically to the lesion once to twice daily. Squeeze 1cm 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 DAKTACORT (or subsequently with DAKTARIN) should be continued without interruption until the lesion has completely disappeared (usually after 2 to 5 weeks). DAKTACORT cream is particularly indicated for the initial stages of treatment.

Discontinue DAKTACORT 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. DAKTACORT 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 DAKTACORT 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.

DAKTACORT can damage certain synthetic materials. Therefore, it is recommended that cotton underwear be worn where clothing contacts with 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

DAKTACORT is generally well tolerated.

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

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

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 at 2°C to 8°C. (Refrigerate. Do not freeze).

MEDICINE CLASSIFICATION

Restricted Medicine.

PACKAGE QUANTITIES

15 g 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.

DAKTACORT cream has a pH of 2.6 - 3.6 and contains benzoic acid, butylated hydroxyanisole and disodium edetate as preservatives.

NAME AND ADDRESS

Johnson & Johnson Pacific (NZ) Ltd
Ground Floor, Ericsson House
105 Carlton Gore Road
Newmarket
Auckland

DATE OF PREPARATION

13 April 2000