

Data Sheet

BATRAFEN CREAM AND SOLUTION

Name of Medicine

Ciclopirox olamine 1% cream and 1% w/v solution.

Presentation

Batrafen Cream is a nearly white cream and each gram contains 10mg ciclopirox olamine in an oil-in-water emulsion consisting of 2-octyldodecanol, mineral oil, stearyl alcohol, cetyl alcohol, polysorbate 60, myristyl alcohol, cocamide DEA, sorbitan monostearate, lactic acid, purified water and benzyl alcohol (1%).

Batrafen Solution is a clear solution and each ml contains 10mg ciclopirox olamine dissolved in alcoholic aqueous solution.

Uses

Actions

Ciclopirox olamine is a broad spectrum antimycotic with a high penetrating power. It has a fungicidal effect on dermatophytes, yeasts, moulds and other fungi.

Pharmacokinetics

Penetration studies in human cadaverous skin from the back, with Batrafen Cream 1% tagged with ciclopirox olamine, showed the presence of 0.8 to 1.6% of the dose in stratum corneum, 1.5 to 6 hours after application.

The levels in the dermis were still 10 to 15 times above the minimum inhibitory concentrations.

Three grams of the 1% solution were applied topically to an area of about 750 square centimetres on the back of male subjects for 6 hours. During this time the serum concentration rose to $0.008 \pm 0.005 \mu\text{g/mL}$. Three to 6 hours after removal of the solution, the concentrations had already fallen below the detection limit of $0.003 \mu\text{g/mL}$.

Of the radioactivity applied, $1.1 \pm 0.6\%$ was eliminated in the urine and $<0.1\%$ in the faeces; the elimination half life was $3.5 \pm 1.1 \text{ H}$ on the first day. Excretion was complete on the second and third day. The absorption which can be regarded as equal with the portion of $1.1 \pm 0.6\%$ eliminated in the urine, practically ended when the active substance was removed from the skin.

Indications

Batrafen is indicated for the topical treatment of dermal infections including tinea pedis, tinea cruris and tinea corporis due to *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Epidermophyton floccosum* and *Microsporum canis*, candidiasis due to *Candida albicans* and tinea (pityriasis) versicolor due to *Malassezia furfur*.

Dosage and Administration

Batrafen Cream: apply on average twice daily to the affected areas and allow to dry. It is recommended that the treatment be carried out until the symptoms have subsided (usually 2 weeks). To prevent a recurrence, continuation is advisable for a further 1 to 2 weeks.

Batrafen Solution: apply twice daily to the affected areas and rub in gently. Clinical improvement with the relief of pruritis and other symptoms usually occurs within the first week of treatment. Patients with tinea versicolor usually exhibit clinical and mycological clearing after two weeks of treatment. To prevent further recurrences it is advisable to continue treatment for a further 1-2 weeks after the disappearance of all clinical symptoms.

Contraindications

Hypersensitivity to any Batrafen component.

Batrafen is not suited for application to the eyes.

Batrafen Cream contains a paraffin, which can cause leaking or breaking of latex condoms. Contact between Batrafen Cream and latex condoms must, therefore, be avoided, because the protection afforded by the condoms may otherwise be lost.

Warnings and Precautions

Draize Human Sensitization Assay, 21 day Cumulative Irritancy Study, Phototoxicity Study and Photo-Draize Study conducted in a total of 142 healthy male subjects showed no contact sensitization of the delayed hypersensitivity type, no irritation, no phototoxicity and no photo-contact sensitization due to Batrafen Cream 1%.

Patients should be advised to use the medication for the full treatment time and advise the physician if there is no improvement after 4 weeks.

Patients should be advised to inform the physician if the area of application shows signs of increased irritation indicative of possible sensitization.

Avoid the use of occlusive dressings.

Animal studies have shown no carcinogenic or mutagenic effects.

Batrafen Cream or Solution should not be used in pregnancy, nor in neonates or infants, without careful consideration of the need for it.

It is not known whether the medicine is excreted in breast milk.

Not for vaginal use.

Batrafen Cream or Solution must not be applied to the eye.

Adverse Effects

In rare cases with Batrafen Cream, transient local reactions e.g. pruritus or a burning sensation, may occur as may allergic contact dermatitis.

In isolated cases with Batrafen Solution, transient local reactions e.g. pruritus or a burning sensation may occur as may – rarely – allergic contact dermatitis.

Interactions

Nil known.

Overdosage

There is no experience of overdose with ciclopirox preparations. However, no relevant systemic effects would be expected to occur if Batrafen Cream or Solution were applied to large areas or used too frequently.

Pharmaceutical Precautions

Shelf Life

Cream

Store at room temperature (below 30°C).

Solution

Store below 25°C and protect from light

Medicine Classification

Pharmacy Only Medicine.

Package Quantities

Batrafen Cream 20g tubes.

Batrafen Solution 20ml plastic bottles.

Further Information

Nil

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Date of Preparation

4 June 2009