New Zealand
DATA SHEET

DP FUSIDIC ACID Cream
fusidic acid 20 mg/g (2 %) cream

Presentation

DP Fusidic Acid Cream is a smooth and white cream which contains 20 mg fusidic acid in each gram of cream.

Uses

Actions
Fusidic acid is a potent antibacterial agent. Fusidic acid and its salts show fat and water solubility and strong surface activity and exhibit unusual ability to penetrate intact skin. Concentrations of 0.03 - 0.12 mcg fusidic acid per ml inhibit nearly all strains of Staphylococcus aureus. Topical application of fusidic acid is also effective against streptococci, corynebacteria, neisseria and certain clostridia.

Pharmacokinetics
In vitro studies show that fusidic acid can penetrate intact human skin. The degree of penetration depends on factors such as the duration of exposure to fusidic acid and the condition of the skin. Fusidic acid is excreted mainly in the bile with little excreted in the urine.

Indications
Indicated either alone or in combination with systemic therapy, in the treatment of primary and secondary skin infections caused by sensitive strains of Staphylococcus aureus, Streptococcus spp and Corynebacterium minutissimum. Primary skin infections that may be expected to respond to treatment with fusidic acid applied topically include: impetigo contagiosa, superficial folliculitis, sycosis barbae, paronychia and erythrasma; also such secondary skin infections as infected eczematoid dermatitis, infected contact dermatitis and infected cuts / abrasions.

Dosage and Administration

Adults and Children
Uncovered lesions – apply gently three or four times daily.
Covered lesions – less frequent applications may be adequate.
**Contraindications**

Infection caused by non-susceptible organisms, in particular, Pseudomonas aeruginosa. DP Fusidic Acid Cream contraindicated in patients with hypersensitivity to fusidic acid and its salts.

**Warnings and Precautions**

Bacterial resistance has been reported to occur with the use of fusidic acid applied topically. As with all topical antibiotics, extended or recurrent application may increase the risk of contact sensitisation and the development of antibiotic resistance. Fusidic acid does not appear to cause conjunctival irritation in experimental animals. Caution should be exercised, however, when DP Fusidic Acid Cream is used near the eyes.

**Preclinical Safety Data**

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the Data Sheet.

**Pregnancy and Lactation**

There is inadequate evidence of safety in human pregnancy. Animal studies and many years of clinical experience have suggested that fusidic acid is devoid of teratogenic effect. There is evidence to suggest that when given systemically, fusidic acid can penetrate the placental barrier. The use of topical fusidic acid in pregnancy requires that the potential benefits be weighed against the possible hazards to the foetus. Safety in nursing mothers has not been established.

**Effects on Ability to Drive and Use Machines**

Not applicable.

**Adverse Drug Reactions**

Hypersensitivity reactions to the active ingredient in the form of skin rashes; mild stinging and irritation on application have been reported rarely.

DP Fusidic Acid Cream is generally well tolerated and not associated with any serious side effects. However, a mild stinging and irritation may be experienced for a short time after application. If you experience prolonged irritation of the skin or any other ill effects, tell your pharmacist or doctor and ask if you should continue with your medication.
Interactions

Not applicable.

Overdosage

Not applicable.

Pharmaceutical Precautions

Store below 25 °C, protect from light and moisture. Keep away from children.

Medicine Classification

Prescription Medicine

Package Quantities

Aluminium tubes of 15 gram.

Further Information

List of Excipients

Liquid paraffin, white soft paraffin, cetyl alcohol, glycerol, polysorbate 60, potassium sorbate, butyldroxyanisole and water

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