

PIMAFUCORT®

Hydrocortisone, natamycin and neomycin sulphate

Presentation

Cream per gram: 10mg hydrocortisone, 10mg natamycin and neomycin sulphate, corresponding to 3.5mg neomycin.

Ointment per gram: 10mg hydrocortisone, 10mg natamycin and neomycin sulphate, corresponding to 3.5mg neomycin.

Uses

Actions

PIMAFUCORT contains as active principle hydrocortisone, a weak corticosteroid with anti-inflammatory and vasoconstrictive actions. The inflammatory reaction and the symptoms of various dermatoses which are often accompanied by itching, are suppressed without curing the underlying diseases.

Moreover PIMAFUCORT contains the broad-spectrum antibiotic neomycin which is active against several Gram-positive bacteria (such as staphylococci and enterococci) and a number of Gram-negative bacteria (such as Klebsiella, Proteus species and E.coli). Pseudomonas aeruginosa is *in vitro* resistant to neomycin.

In addition to hydrocortisone and neomycin PIMAFUCORT contains natamycin, which has a fungicidal action against yeast infections, in particular Candida infections.

Pharmacokinetics

Natamycin and neomycin are not significantly absorbed through normal skin or mucous membranes. Some absorption of neomycin may occur through damaged skin, wounds and ulcers. About 1-3% of the hydrocortisone applied is absorbed through normal skin. The absorption through eczematous skin is approx. double, while the absorption through severely infected skin may be five times the normal value. In children the absorption decreases with age.

Indications

Short-term treatment of superficial dermatoses which are sensitive to corticosteroids, but not primarily caused by micro-organisms, if these are complicated by secondary bacterial and candidal infections sensitive to neomycin or natamycin.

Dosage And Administration

PIMAFUCORT should be applied sparingly to the affected area 2-4 times daily. Treatment should not be continued for longer than 14 days.

For treatment of acute and subacute skin disorders and for treatment of disorders of hirsute areas and those in the skin folds, PIMAFUCORT cream should preferably be used, whereas in the treatment of chronic disorders of the skin with scaly, dry or fissured skin lesions, and for seborrhoea in particular, PIMAFUCORT ointment should be applied.

Contraindications

Because PIMAFUCORT contains the weak corticosteroid hydrocortisone the following contraindications apply:

- Skin disorders caused by:
 - primary bacterial infections
 - viral infections
 - primary fungal and yeast infections
 - parasitic infections
- Ulcerous skin disorders, wounds, ulcers cruris, burn wounds.
- Side-effects caused by corticosteroids (dermatitis perioralis, striae atrophicae).
- Ichthyosis, juvenile dermatosis plantaris, acne vulgaris, acne rosacea, fragility of skin vessels, skin atrophy.

In addition PIMAFUCORT should not be used in cases of:

- Allergic hypersensitivity to components of the vehicle, neomycin, and natamycin or corticosteroids (which rarely occurs).

Warnings And Precautions

Only in specific conditions is a combination of a corticosteroid, antimycotic and antibiotic indicated. Good diagnostic skills are required to exclude insensitivity of the micro-organism. In some cases a combination of two or more active substances is necessary. However, often a simple preparation is sufficient.

Do not apply to eyelids because of the possibility of contaminating the conjunctiva. This may cause glaucoma simplex or subcapsular cataract. If PIMAFUCORT is applied to extensive skin areas in children or under occlusion, the possibility of inhibition of adrenocortical function should be considered (insufficient experience of these applications is available).

Cross-hypersensitivity between neomycin and chemically related antibiotics, such as kanamycin, paromomycin and gentamicin may occur. Cross-resistance between neomycin and other antibiotics belonging to the aminoglycoside group may occur.

Long-term application and application to wounds or damaged skin should be avoided because of a theoretical risk for ototoxicity and nephrotoxicity after absorption of neomycin.

If superinfection or overgrowth with fungi occurs, treatment with the preparation should be suspended and the necessary countermeasures should be taken.

Pregnancy And Lactation

There is a theoretical risk of foetal ototoxicity when neomycin-containing preparations are used during pregnancy. PIMAFUCORT should not be applied on large skin surfaces of pregnant women, for long periods or under occlusion.

Effects On Ability To Drive And Use Machines

There are no data concerning the effect of PIMAFUCORT on the ability to drive and use machines, but PIMAFUCORT is not expected to exert any influence.

Adverse Effects

Local Effects

After application of PIMAFUCORT a slight exacerbation of the lesion may appear initially. This does not necessitate discontinuation of treatment.

- contact allergy, in particular by neomycin
- the following side-effects of corticosteroids might occur, but the chance is less with hydrocortisone than with the use of stronger corticosteroids:
 - skin atrophy, often irreversible, with thinning of the skin, teleangiectasia, purpura and striae
 - rosacea-like and perioral dermatitis with or without skin atrophy
 - "rebound effect", which may lead to dependence on steroids
 - delay of the healing process
 - effects on the eye; increase of the intraocular pressure, increase of the chance of cataract
 - depigmentation, hypertrichosis
 - contact allergy (seldom)

The chance of local side-effects increases with the duration of treatment. Application under occlusion (plastic, skin folds) also increases this chance. The face, the hairy skin and the skin of the genitals are particularly sensitive to local effects.

With inappropriate use, bacterial, parasitic, fungal and viral infections may be masked and/or worsen.

Systemic Effects

Systemic side-effects (inhibition of adrenal function) following topical application of corticosteroids are rarely experienced in adults and are not likely to occur with PIMAFUCORT. The possibility of systemic effects is greatest following application under occlusion, on large skin areas, for a long period and in children.

Interactions

Not known.

Overdosage

Not known. In practice, it is unlikely that toxic doses of neomycin can be absorbed, unless it is used in the ear and the ear drum is perforated. Occasional intake of the complete contents of one pack of PIMAFUCORT may probably be tolerated without toxic effects.

Pharmaceutical Precautions

PIMAFUCORT cream and ointment should be stored at <25°C.

Medicine Classification

Prescription Medicine

Package Quantities

Tubes of 15g cream or ointment.

Further Information

List Of Excipients

Cream - trisodium citrate, emulgade F special, sorbitan monostearate, cetyl ester wax, decyl oleate, macrogol stearate 100, methylparahydroxybenzoate, propylparahydroxybenzoate, water.
Ointment - polyethylene oleogel (liquid paraffin with 5% w/w polyethylene).

Incompatibilities

No particulars.

Shelf-Life

PIMAFUCORT should not be used after the expiry date. At the recommended storage temperature and in the pack in which it is sold, PIMAFUCORT cream can be kept for 3 years and PIMAFUCORT ointment for 5 years.

Name And Address

CSL Biotherapies (NZ) Ltd
666 Great South Rd
Central Park
Auckland
New Zealand

Ph: 0800 502 757

Date of Preparation

19 February 2008

PIMAFUCORT[®] is a registered trademark of Astellas Pharma Europe B.V.