# NEW ZEALAND DATA SHEET

## 1. PIMAFUCORT®

Ointment

Hydrocortisone, natamycin and neomycin sulphate

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

**Ointment** per gram: 10mg hydrocortisone, 10mg natamycin and to 3.5mg neomycin (as neomycin sulphate).

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

**Ointment**

Description of the medicinal product: whitish ointment.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic 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.

### 4.2 Posology and method of administration

Pimafucort should only be used in specific conditions when a combination of a corticosteroid, antimycotic and antibiotic is clinically indicated. For many conditions, a product containing a single active ingredient is sufficient. Pimafucort® should be applied sparingly to the affected area 2-4 times daily. Treatment should be for short term use only. Treatment should not be continued for longer than 14 days. Pimafucort should not be applied to the genital areas such as under the foreskin due to risk of local skin reactions (see section 4.4).

For treatment of chronic disorders of the skin with scaly, dry or fissured skin lesions, and for seborrhoea in particular, Pimafucort® ointment should be applied.

## 4.3 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, ulcera 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).

## 4.4 Special warnings and precautions for use

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.

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Local skin reactions
Sensitivity reactions (often related to the neomycin component) such as rash or ulcerations may occur with Pimafucort use when applied, particularly to sensitive areas (see section 4.8).
Pimafucort should not be applied to the genital areas including the foreskin region due to risk of local reactions. Alterative treatment should be used.

## 4.5 Interaction with other medicinal products and other forms of interaction

Not known.

## 4.6 Fertility, 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.

## 4.7 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.

## 4.8 Undesirable 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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/

### 4.9 Overdose

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.

Contact the Poisons Information Centre on 0800 POISON or 0800 764 766 for further advice on overdose management.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, mildly effective, combination with antibiotics

ATC code: DO7CA

Mechanism of action

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.

### 5.2 Pharmacokinetic properties

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.

### 5.3 Preclinical safety data

No specific data are available.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Ointment - polyethylene oleogel (liquid paraffin with 5% w/w polyethylene).

### 6.2 Incompatibilities

Not applicable.

### 6.3 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® ointment for 5 years.

### 6.4 Special precautions for storage

Pimafucort® ointment should be stored below 25°C.

### 6.5 Nature and contents of container

Aluminium tubes of 15g ointment.

## 7. MEDICINE SCHEDULE

Prescription Medicine

## 8. SPONSOR

LEO Pharma Ltd

Auckland

New Zealand

New Zealand Toll Free No. 0800 497 456

## 9. DATE OF FIRST APPROVAL

Ointment - 31 December 1969

## 10.DATE OF REVISION OF TEXT

27 August 2024



**Summary Table of Changes**

| Section changed | Summary of new information |
|---|---|
| Section 8 | Change of sponsor address |
| Sections 1, 2, 3, 4, 6, 9 and 10 | Removal of Pimafucort cream information |
| **Sections 4.2 and 4.4** | **additional information about Pimafucort when applied to the genital area and to reinforce that use of a combination cream should only be used when clinically indicated** |