

Consumer Medicine Information

PIMAFUCORT[®]

**1% Hydrocortisone, 1% Natamycin and 0.35% Neomycin
Cream and Ointment**

What is in this leaflet

This leaflet answers some common questions about PIMAFUCORT Cream and Ointment. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the expected benefits.

Use PIMAFUCORT as instructed. **If you have any concerns about using this medicine, ask your doctor or pharmacist.**

Keep this leaflet. You may need to read it again.

What PIMAFUCORT is used for

PIMAFUCORT is used on the skin to relieve the itching and discomfort of many skin problems where these also have an added bacterial and/or candidal (fungal) infection

PIMAFUCORT contains the medicines:

- hydrocortisone: a corticosteroid which relieves inflammation of the skin,
- neomycin: an antibiotic which is active against bacterial infections and
- natamycin: an antifungal which is active against yeast infections, particularly Candida infections.

Your doctor may have prescribed PIMAFUCORT for another reason. Ask your doctor why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you use PIMAFUCORT

When you must not use PIMAFUCORT.

Do not use this medicine if you have:

1. **an allergy to:**
 - **any medicine containing hydrocortisone, natamycin or neomycin sulphate** (or related antibiotics belonging to the aminoglycoside group, such as kanamycin, framycetin, paromomycin and gentamicin).
 - **any of the ingredients listed at the end of this leaflet (see Product Description).**

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

2. a skin disorder *caused* in the first instance by a:
 - bacterial infection
 - viral infection
 - fungal or yeast infection
 - parasitic infection
3. ulcers on the skin, wounds or burns
4. experienced side effects caused by other corticosteroids (such as dermatitis around the mouth or stretch marks)
5. any of the following skin problems:
 - Ichthyosis (a condition causing rough, fish-scale like skin)
 - Juvenile plantar dermatosis (a skin problem on the feet of children)
 - Common acne or acne rosacea
 - Fragile blood vessels
 - Thinning of the skin

Ask your doctor or pharmacist to be sure you do not have any of these conditions.

Do not use this medicine just before having a bath, shower or going swimming. If you do, you may reduce the effectiveness of PIMAFUCORT.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use PIMAFUCORT

Tell your doctor if:

1. you have any other skin disorders.
2. you have a known allergy to PIMAFUCORT or any ingredients listed at the end of this leaflet.
3. you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes
4. you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the potential risks and benefits involved in using PIMAFUCORT.

If you have not told your doctor about any of the above, tell him/her before you start using this medicine.

There is no evidence that PIMAFUCORT is addictive.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may interfere with PIMAFUCORT.

These medicines may be affected by PIMAFUCORT or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use PIMAFUCORT

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to use

PIMAFUCORT should be applied sparingly to the affected area 2-4 times daily.

Treatment should not be continued for longer than 14 days.

When to use PIMAFUCORT

Use your medicine at about the same time each day for optimum effect. It will also help you remember when to use it.

How to use PIMAFUCORT

PIMAFUCORT is to be applied to the skin.

It is important to use PIMAFUCORT exactly as your doctor or pharmacist has told you. If you use it less often than you should, it may not work as well and your skin problem may not improve. Using it more often than you should may not improve your skin problem any faster and may cause or increase side effects.

How long to use PIMAFUCORT

Follow carefully all directions given to you by your doctor and the pharmacist. These directions may differ from the information contained in this leaflet.

Do not use this medicine for longer than your doctor tells you. If you use this medicine for longer than your doctor or pharmacist tells you, the chance of side effects may increase.

If you are unsure how long to use PIMAFUCORT, ask your doctor or pharmacist for help.

If you forget to use PIMAFUCORT

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Otherwise, use it as soon as you remember, and then go back to using your medicine as you would normally.

Do not use a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your doctor or pharmacist for some hints.

While you are using PIMAFUCORT

Things you must do

Tell all doctors and pharmacists who are treating you that you are using this medicine.

If you feel that this medicine is not helping your condition, tell your doctor.

Tell your doctor if, for any reason, you have not used this medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

If you become pregnant while using this medicine, tell your doctor immediately.

Things you must not do

Do not use this medicine under dressings or on large areas of skin unless your doctor tells you.

Do not use this medicine in or near the eyes.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they seem to have the same condition as you.

Things to be careful of

Do not use large amounts of this medicine for a long time. If you use large amounts for a long time, the chance of absorption through the skin and the chance of side effects increase.

Avoid application of this medicine on wounds or damaged skin. If you use this medicine on wounds or damaged skin, the chance of side effects increases.

In children the application of topical steroids, such as PIMAFUCORT, should be limited as much as possible.

Ask your doctor or pharmacist if you are concerned about the length of time you have been using this medicine.

Side-Effects

Like all medicines, PIMAFUCORT can cause some side effects. Side effects not listed in this leaflet may occur in some patients.

Tell your doctor or pharmacist if you have any unpleasant effects while you are using PIMAFUCORT even if you do not think the effect is connected with the medicine or is not listed in this leaflet.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- aggravation of the lesion

This is a common side effect of your medicine. (It is usually mild and short-lived.)

Tell your doctor as soon as possible if you notice any of the following local effects:

- burning, itching or irritation of the skin at the site of contact with the medicine, this may mean you have a contact allergy. Contact allergy is most likely to develop to the neomycin antibiotic

The following side effects of corticosteroids may occur. However this is less likely with PIMAFUCORT than with the stronger corticosteroids:

- thinning, discolouration or depigmentation of the skin
- reddening of the skin or skin rash
- worsening of the original skin problem when the PIMAFUCORT is stopped. This is known as the "rebound effect"
- delayed wound healing.
- eye problems (eg increased pressure in the eye, which may have no symptoms but is found on testing; and increased chance of cataract, which interferes with vision)
- increased body hair
- allergy on contact: this is rare

The above list includes serious side effects, which may require medical attention. Usually they are caused by continued use on large areas of skin, however serious side effects are rare. The chance of experiencing side effects is increased if PIMAFUCORT is used with a dressing or in skin folds.

The skin on the face, skin areas covered in hair and the skin of the genitals are especially sensitive to local effects.

If PIMAFUCORT is used incorrectly, bacterial, parasitic, fungal and viral infection may be masked and/or aggravated.

Tell your doctor as soon as possible if you notice any change in your appearance or health and it worries you. Rarely there may be signs of imbalance to the adrenal gland hormones which may be serious. The risk of such side effects is highest when:

- the treated area is covered with a dressing or in a skin fold
- PIMAFUCORT is applied on large surfaces
- long-term treatment occurs
- application occurs in children who are more susceptible to this side effect.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

In case of Overdose

If you swallow PIMAFUCORT

Immediately telephone your doctor or the Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this

even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

After using PIMAFUCORT

Keep PIMAFUCORT in its pack until required.

Storage

Store PIMAFUCORT in a cool dry place at normal room temperature (not more than 25°C).

Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep PIMAFUCORT where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not use PIMAFUCORT after the expiry date on the package.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What PIMAFUCORT looks like

PIMAFUCORT **Cream** is a light cream coloured cream

PIMAFUCORT **Ointment** is a light cream coloured ointment

Ingredients

Active ingredients:

PIMAFUCORT Cream and Ointment contain:

Hydrocortisone 10 mg/g

Natamycin 10 mg/g

Neomycin sulphate corresponding to neomycin 3.5 mg/g

Inactive ingredients:

PIMAFUCORT Cream also contains:

- sodium citrate (anhydrous)
- emulgade F special
- sorbitan monostearate
- cetyl esters wax
- decyl oleate
- macrogol stearate 100
- methyl parahydroxybenzoate
- propyl parahydroxybenzoate
- purified water

PIMAFUCORT Ointment also contains:

- Polyethylene oleogel (liquid paraffin gel, polyethylene)

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

This is not all the information available on PIMAFUCORT. If you have any more questions or are unsure about anything, ask your doctor or pharmacist.

Supplier

PIMAFUCORT is supplied in New Zealand by:

CSL Biotherapies (NZ) Ltd
666 Great South Road
Penrose
Auckland 6
NEW ZEALAND

Telephone: 0800 502 757

This leaflet was prepared in February 2008.

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