

 PACKAGE LEAFLET:
Information for the patient

FLUODERMA

Cream – (0.2 mg + 5 mg) / 1 g
(Flumethasone pivalate, Neomycin sulphate)

Read this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Fluoderma is and what it is used for
2. Before you use Fluoderma
3. How to use Fluoderma
4. Possible side effects
5. How to store Fluoderma
6. Other information

1. WHAT FLUODERMA IS AND WHAT IT IS USED FOR

Flumethasone pivalate, one of the active substances of Fluoderma – cream, is a moderately potent glucocorticoid, which is used topically. It has anti-inflammatory, antiallergic, vasoconstrictor and antiproliferative activity. In inflammatory skin diseases of different types and origins, flumethasone pivalate provides a rapid relief and eliminates symptoms such as itching. Multiple effects that provide corticosteroids are related with a complex molecular mechanism, where binding with specific cytoplasmic receptors plays an important role. Neomycin is an aminoglycoside antibiotic which is active against many gram-positive and gram-negative bacteria. It may cause sensitization more easily than other antibiotics, when it is used locally.

Fluoderma is indicated in initial treatment of inflammatory skin diseases of different types and localization, which respond to corticosteroids and where a secondary infection caused by organisms susceptible to neomycin sulphate appears, such as seborrheic eczema, contact eczema, atopic dermatitis (in patients of all ages), localized neurodermatitis, intertrigo, superficial pyoderma (e.g. impetigo) and insect bites associated with secondary infections. Your doctor may have given Fluoderma for another purpose. Ask your doctor if you want to know why you were given Fluoderma.

2. BEFORE YOU USE FLUODERMA

Do not use Fluoderma if you:

- are hypersensitive to flumethasone or to corticosteroids in general;
- are hypersensitive to neomycin sulphate;
- are allergic to any of the inactive ingredients, listed at the

end of this leaflet;

- have viral skin diseases (such as varicella, exanthema after vaccination, herpes simplex, herpes zoster);
- have tuberculosis of the skin;
- are suffering from syphilis;
- have dermatitis around the mouth;
- have rosacea and peribuccal dermatitis;
- have acne vulgaris.

Do not apply Fluoderma in the eye.

If you think that you have any of the conditions mentioned above, do not use the cream, talk to your doctor first and follow his advices.

Take special care with Fluoderma

Use of the drug in small children should be done in very special cases.

In areas such as face, genital area, or hairy surface, the drug should be used with caution, in small areas and not longer than a week.

In cases of prolonged use and in large quantities, the patient should control the production of endogenous corticosteroids. In very special cases, the preparation may be used in large areas of skin or under occlusive dressing, but only in patients who are under medical supervision. However the use in large surface or damaged skin, as well as long-term treatment should be avoided.

Fluoderma should not be applied for more than 2 to 3 weeks without interruption.

If there are no improvements observed within 7 days, the treatment should be revised.

Inform your doctor if:

- the child who is going to use this medicine is at an early age;
- you are allergic to other drugs, especially if they are in the same class of drugs with Fluoderma;
- you are pregnant or planning to become pregnant while you are using Fluoderma;
- you are breastfeeding or planning to breastfeed.

Taking other medicines

Until now, there are no known interactions of Fluoderma – cream with other drugs. This is also due to the fact that this drug is only for local use. Contemporaneous experience also shows that it is not observed any apparent absorption of flumethasone pivalate from the skin, a fact which excludes the possibility of any interaction with other drugs.

Using Fluoderma with food and drinks

The food does not affect the absorption of Fluoderma.

Pregnancy and breastfeeding

Inform your doctor or pharmacist if you are pregnant or planning to become pregnant because the use of Fluoderma cream should be done carefully, especially in the first 3 months of pregnancy. The doctor or pharmacist will discuss on the risks and benefits of using it during pregnancy. Ask your doctor or pharmacist for advice before you use this medicine during pregnancy or breastfeeding. If your doctor thinks it is reasonable that you should use this drug, then you should follow his advice.

Driving and using machines

Be careful while driving or using machinery until you see how Fluoderma affects you, although there are no data showing that it affects the psychophysical abilities to use machines.

Important information about some of the excipients of Fluoderma

This drug contains methyl hydroxybenzoate which may cause allergic reactions (possibly delayed).

3. HOW TO USE FLUODERMA

This medicine should be used in the affected area 2 to 3 times daily, in the form of a thin layer, depending on the severity of the disease. The cream may be rubbed carefully on the skin. If it is necessary, the affected area may be covered with a porous dressing. Generally it is not necessary to use a dressing at all. However, in cases where the effect is not satisfactory or in refractory cases, the effect may be intensified by applying short-term dressing. Treatment of chronic skin diseases (e.g. psoriasis, chronic eczema) should not be discontinued immediately. This medicine should not be applied for more than 2 – 3 weeks without interruption.

Always use Fluoderma – cream exactly as your doctor has advised you. If you notice that the effects of Fluoderma are too strong or too weak, talk to your doctor or pharmacist. Your doctor may ask you to use Fluoderma for a long time. Ask your doctor for advice if you are not sure for how long you should use it.

If you use more Fluoderma than you should

If you use more Fluoderma than you should, or if the children take it accidentally, please contact your doctor.

If you forget to use Fluoderma

If you forget to use one dose, use the next dose in its usual time. Do not use a double dose to make up the forgotten dose(s).

If you have further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

All medicines may cause side effects. Sometimes they are serious, most of the times not. Do not be alarmed by this list of possible side effects. You may not get any of them.

Inform your doctor if any of the following side effects concerns you:

- local irritation, such as burning sensation, itching or skin exanthema; in some cases is observed a slight atrophy of the skin;
- contact allergies, changes in skin pigmentation;
- striae distensae rubrae, telangiectasia, purpura or steroid acne may occur during prolonged use in large areas or under occlusive dressing or in areas where the skin is more permeable or damaged.

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE FLUODERMA

Keep this medicine out of the sight and reach of children! Do not use Fluoderma after the expiry date which is stated

on the package.

Do not store above 25°C!

6. OTHER INFORMATION

What Fluoderma contains

The active substances are Flumethasone pivalate and Neomycin sulphate.

Each gram cream contains 0.2 mg (0.02%) of flumethasone pivalate and 5 mg (0.5%) of neomycin sulphate.

Other ingredients: macrogol stearate, glycerol monostearate, light liquid paraffin, methyl hydroxybenzoate, ethanol, essence rose, purified water.

Contents of the pack

Box with 1 tube of 15 g.

Explanatory of the illustration icons on the packaging:

 Ask your doctor or pharmacist.

 Content.  Warning.

 Cream.

Marketing Authorisation Holder and Manufacturer:

 **PROFARMA Sh.a.**
Rruga "Myslym Keta"
Tel.: 00355 4 23 89 602
Tirana - ALBANIA

This leaflet was last revised in July 2012.

 SPECIFICATION

 CROPPING AREA 12 x 19 cm

PAY ATTENTION, all the layers are visible.

If you have to print this document please check or uncheck the specific layers.