

PACKAGE LEAFLET: INFORMATION FOR THE USER

AFLODERM

0.5 mg/g, ointment

ALCLOMETASONE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• 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 you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What Afloderm is and what it is used for
2. Before you take Afloderm
3. How to take Afloderm
4. Possible side effects
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1. WHAT AFLODERM IS AND WHAT IS USED FOR?

AFLODERM ointment contains alclometasone which belongs to a group of moderately strong local corticosteroids intended for use on the skin. AFLODERM is used to relieve redness and itching that occur with some skin diseases such as atopic and contact dermatitis (inflammatory diseases of the skin), and psoriasis (chronic disease of the skin with the appearance of redness and peeling skin). AFLODERM is particularly suitable for:

- application to sensitive parts of the body (face, armpit, and groin)
- treatment of chronic skin diseases in patients with sensitive skin (children and elderly persons)
- application to large areas of the skin (especially in children because in this way the possibility of side effects due to the passing of corticosteroids through the skin into the bloodstream is reduced)
- continuation of treatment initiated with strong corticosteroids for use on the skin.

2. BEFORE YOU TAKE AFLODERM

Do not use AFLODERM:

- if you are hypersensitive to alclometasone or some of the ingredients of the medicinal product

- if you suffer from acne, skin tuberculosis, viral infections of the skin (especially herpes), vaccinia, varicella (chickenpox), perioral dermatitis and rosacea.

Take special care with AFLODERM ointment

- in case of allergic reactions (symptoms of itching, burning and redness) during the application of AFLODERM ointment, stop applying the medicine and contact your doctor.
- use in children must be carried out with caution and during the shortest period of time, because the large area of the skin compared to the body weight and incompletely developed skin may cause the passing of large amounts of applied medicine through the skin and systemic adverse effects. The ointment should not be applied under the diapers (especially if they are plastic) because diapers are acting as barrier bandage, which can also lead to excessive entering of the medicine through the skin.
- AFLODERM ointment is not recommended for long-term application of on large areas of skin, especially under the bandages. Patients who need long-term treatment with AFLODERM, especially with the use of bandages, they must be under the constant doctor's supervision, due to the possible occurrence of systemic effects of the medicine.
- do not use AFLODERM in the eye or near the eye due to the possibility of the occurrence of cataracts (cataract) or elevated intraocular pressure (glaucoma).
- in case of fungal, or bacterial Super-infections of skin changes (increase in micro-organisms different from the kind that was treated at the beginning) additional local application of the corresponding medicinal product which will be recommend by your doctor is required.
- some places on the body, such as groin, armpits and the area around the anus, are more susceptible to the onset of stretch marks in the local treatment of AFLODERM ointment, therefore the application to these areas should be as short as possible.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before taking any medicine. Local application of AFLODERM in pregnant women is allowed only in cases where, according to the doctor, the possible benefit for a pregnant woman surpasses possible risks for the fetus. In these cases, the application must be short-term and limited to a small body surface. According to the decision of a doctor, AFLODERM ointment can be applied if you are breast-feeding, but it should not be applied to the skin of the breasts before breastfeeding.

Important information about some of the ingredients of AFLODERM ointment

The ointment contains cetyl and stearyl alcohol, chlorocresol and propylene glycol. Cetyl and stearyl alcohol can cause local skin reactions (i.e., contact dermatitis), allergic reactions, chlorocresol and propylene glycol may irritate the skin.

3. HOW TO TAKE AFLODERM

Always use AFLODERM exactly as told by your doctor. Check with your doctor or pharmacist if you are not sure.

AFLODERM ointment is intended only for external use on the skin.

Ointment is applied in the treatment of chronic (long-term) dermatoses such as dry, scaly lesions and lichens or in case when the protective effect of ointment is required.

Apply the amount of AFLODERM ointment which is required to cover the sick skin surface two to three times a day in a thin layer and rub it gently.

The surface of the skin to which you apply AFLODERM ointment should not cover because of the possibility of increased effect, except in cases determined by the doctor.

Use in children should be conducted through the shortest possible time (2-3 weeks) and with caution.

If you use more AFLODERM ointment than you should

Never apply more AFLODERM ointment than your doctor prescribed. If you have used large amounts of ointment or if you have used it over a longer period than prescribed, immediately consult your doctor or pharmacist.

If you, or someone else, accidentally swallows the ointment, call your doctor.

If you forget to apply AFLODERM ointment

If you forget to apply the ointment, do it as soon as possible, and then continue according to the regular schedule. Do not use an increased amount of AFLODERM ointment to make up for the dose that you missed. If you have any further questions on the use of this medicine, contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, AFLODERM may cause side effects. Side effects that occur with the local application of alclometasone in therapeutic doses are usually mild-mannered, and can be local, site conditions, and systematic, as a consequence of the increased entry of the medicine through the skin into the bloodstream. The local side effects are more common when applying under the bandages. Systemic side effects are extremely rare, mostly at the excessive use of the medicinal product and usually disappear immediately after the termination of the application. Side effects that occur during the application of the alclometasone on the skin in the 1-2% of patients:

- itching
- annealing
- redness
- dry skin
- irritation
- a rash.

Very rare (occurring in less than 1 in 10000 patients):

- atrophy (thinning of the) skin
- stretch marks
- Folliculitis (inflammation of hair root)
- Hypertrichosis (enhanced by the Hairiness of the skin)
- allergic contact dermatitis (redness, swelling and inflammation, the bubbles on the skin)
- changes similar to Acne
- local hypo pigmentation of the skin (reduced amount of melanin pigment in the skin)
- miliaria (disorder of sweat glands)
- superficial vasodilatation (visible enlargement of the blood vessels in the skin, especially on the face)
- secondary infections of the skin.

If you notice any side effects, talk to your doctor or pharmacist.

5. HOW TO STORE AFLODERM

Store out of the reach and sight of children.

Keep AFLODERM in the temperature below 30° C.

Shelf-life of the medicine is 3 years from the date of manufacture indicated on the packaging.

AFLODERM must not be used after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to remove medicines that you no longer need. These measures will help to protect the environment.

6. FURTHER INFORMATION

What does AFLODERM contain?

The active substance is alclometasone. One gram of ointment contains 0.5 mg alclometasone dipropionate. The other ingredients are: hexylene glycol; propylene glycol monopalmistearate; vaseline, white; wax, white.

What AFLODERM looks like and contents of the pack

Colourless to light yellow, homogeneous ointment. 20 g fat, in the aluminum tube with plastic cap, in a box.

Regime of dispensing

The medicine is issued on doctor's prescription.

Manufacturer

BELUPO lijekovi i kozmetika, d.d.
Ulica Danica 5
48 000 Koprivnica, Croatia

Manufacturer of the medicinal product

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