

PACKAGE LEAFLET: INFORMATION FOR THE USER

BELODERM

0.5 mg/g, ointment

BETAMETHASONE

• *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 Beloderm is and what it is used for
2. Before you take Beloderm
3. How to take Beloderm
4. Possible side effects
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1. WHAT IS BELODERM OINTMENT AND WHAT IT APPLIES

BELODERM ointment contains betamethasone, glucocorticoid steroid from a group of strong corticosteroids. BELODERM ointment is applied topically to the skin to minimize redness and itching which are present in some skin diseases such as psoriasis, eczema, various types of dermatitis and Seborrhea.

2. BEFORE YOU USE BELODERM OINTMENT

Do not use BELODERM ointment:

- If you are hypersensitive to betamethasone or any of the ingredients of the medicinal product
- in the treatment of acne, rosacea (disease of the skin with redness of the central part of the face), changes on the skin (dermatitis) in the area around the mouth, itching of the genitals and the area around the anus, tuberculosis of the skin, diaper rash, a viral infection of the skin (especially with herpes), cow pox, and chickenpox.

Be careful with BELODERM ointment

If, when applying the BELODERM ointment, there is redness and itching, or tingling sensation, immediately stop using the medicine and contact your doctor.

Do not use Beloderm ointment below bandages, except when necessary or in children below diapers (especially plastic ones), as it enhances the absorption of the medicine.

Do not apply Beloderm ointment on the face for a long period of time.

Do not use Beloderm ointment in the eye or near the eyes, on genitals and around the body's openings, neither on open wounds and damaged skin (eg, skin sores due to varicose veins of the lower leg).

Some places on the body, such as the groin, armpits and the area around the anus, are more susceptible to the onset of stretch marks in the local treatment with BELODERM ointment; therefore use on these areas should be maximally limited.

In the occurrence of fungal superinfection of skin changes, consult a doctor in order to additionally apply the appropriate medicine.

Taking other medicines with BELODERM ointment

Tell your doctor or pharmacist about all medicines you are taking or have recently taken, including those that you bought without a prescription.

There is no known influence of other medicines on the efficacy of Beloderm ointment, nor vice versa.

Children

In children, the large area of the skin in relation to the body weight and insufficiently developed stratum corneum, may cause the absorption of proportionally larger amounts of locally administered betamethasone and thus unwanted systemic side effects.

In addition, we should keep in mind that the use below the diapers (especially plastic ones), can cause increased absorption, because diapers are acting as impermeable bandage. Use in children should be limited to the shortest time possible, with the utmost caution.

Patients with impaired liver function and patients who need long-term use

In patients with impaired liver function and in patients who need long-term therapy, particularly when applying bandages, special care is also required, because of the possibility of increased absorption of the active substance and the consequent systemic side effects.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before using any medicine.

BELODERM ointment in pregnant and breast-feeding women should be used only when necessary.

The application must be short-term and limited to a small body surface. Medicine should not be applied on the skin of the breasts immediately before breastfeeding.

Driving and using machines

BELODERM ointment has no influence on the ability to drive and use machines.

3. HOW TO TAKE BELODERM OINTMENT

When applying BELODERM ointment strictly follow the instructions given to you by your doctor.

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

Ointment is applied in the treatment of chronic skin diseases (dermatosis) such as for example, dry, scale like lesions, and lichen, or in cases when it a protective effect of ointment is required.

Apply the amount of ointment which is required to cover the affected area of the skin, one to two times a day in a thin layer, and gently rub it.

Thick areas of the skin and places from which the product is easily removed during normal activities (such as the palms and soles), require more frequent application.

Wash your hands after using this medicine, unless you treat the skin of the hands.

How long can you apply BELODERM OINTMENT?

The duration of treatment should not be longer than 3 weeks. With chronic diseases, continue the treatment for some time after the disappearance of all signs of the disease in order to prevent a return of the disease, with a constant medical supervision.

The use in children and the application of BELODERM ointment on the face should not be longer than 5 days.

If you have applied more BELODERM ointment than you should

Never apply more Beloderm than prescribed.

If you have applied medicine in large amounts or over a longer period than prescribed, immediately consult your doctor or pharmacist.

If you forget to use BELODERM ointment

If you miss a dose, apply the next dose at the usual time and continue to use the medicine as instructed by a doctor.

Do not apply a double dose to make up for a forgotten dose.

If you have mistakenly swallowed BELODERM ointment

If you or someone else has mistakenly swallowed BELODERM ointment, tell your doctor immediately.

If you have any further questions on the use of BELODERM ointment, talk to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all other medicines BELODERM ointment may cause side effects.

Side effects that occur in local administration of therapeutic doses of betamethasone are usually mild in nature, and may be local at application site and occur as a result of systemic absorption of the medicine into the circulation.

The local application of betamethasone on the skin may cause the following side effects: thinned skin, stretch marks, dotted bleeding in the skin, visible enlargement of the capillaries in the skin, skin irritation, dry or chapped skin, inflammation of the hair root, increased hairiness of the skin, acne, inflammation of the skin around the mouth, redness, swelling, and inflammatory skin rash, blistering, burning, itching, discoloration of the skin and hair, blockage of the exit channel of sweat glands and skin infection.

Systemic side effects of locally applied betamethasone occur extremely rarely, mostly when you overdose and they usually disappear promptly after discontinuation of treatment.

Children, people who have liver problems or people who require long-term therapy should be under strict supervision of a doctor due to the possibility of increased absorption of the active substance and consequential systemic side effects of treatment.

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

5. HOW TO STORE BELODERM

Keep out of reach and sight of children.

Store at temperature below 25 °C.

Shelf-life of the medicine is 4 years from the date of manufacture indicated on the packaging.
BELODERM ointment should not be used after the expiry date which is stated on the packaging.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What BELODERM ointment contains

The active substance is in the form of betamethasone betametazondipropionat.

One gram of ointment contains 0.5 mg betamethasone in the form of betametazondipropionat.

The other ingredients are: paraffin, liquid; vaseline, white.

How to BELODERM the ointment looks like and contents of the pack

White, semitransparent, homogeneous ointment.

15 g and 30 g of ointment 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.

Danica 5, Koprivnica, Croatia

Manufacturer of the medicinal product

Belupo lijekovi i kozmetika d.d.

Danica 5, Koprivnica, Croatia