

PACKAGE LEAFLET: INFORMATION FOR THE USER

BELOSALIC

(0.5 + 30.0) mg / g ointment

BETAMETHASONE, SALICYLIC ACID

• 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 BELOSALIC tablets is and what it is used for
2. Before you take BELOSALIC
3. How to take use BELOSALIC
4. Possible side effects
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1. WHAT BELOSALIC IS AND WHAT IT IS USED FOR

BELOSALIC contains Betamethasone which is a glucocorticoid steroid from the group of strong corticosteroids. Salicylic acid, the other active ingredient of this medicine helps in the treatment of dry and scaly skin. BELOSALIC ointment is used to relieve the symptoms of inflammation, dryness, itching and discomfort that can occur in psoriasis, dermatitis, eczema, seborrhea, and other changes on the skin that respond to glucocorticoid steroids.

2. BEFORE YOU TAKE BELOSALIC

Do not take BELOSALIC

- If you are allergic to any ingredient of this medicine
- If you have skin tuberculosis, viral infections of the skin (especially in herpes), cowpox, chicken pox, chronic inflammation of the skin around the mouth and redness of the central parts of the face

Take special care with BELOSALIC, so you must tell the doctor if you

- If upon the first application of BELOSALIC ointment hypersensitivity reaction occurs on the skin (itching, burning, redness), administration should be immediately discontinued. BELOSALIC ointment

should not be used under occlusive dressing, except if necessary. Prolonged use of BELOSALIC ointment on the face is not recommended due to possible occurrence of rosacea-like dermatitis, perioral dermatitis and acne.

- Do not use BELOSALIC in the eye or near the eyes, on the genitals and around body openings, nor the open wounds and damaged skin.
- If you have liver problems or if the application BELOSALIC ointment is necessary in a child or for a longer period of time, constant medical supervision is needed.
- Some areas of the body such as the groin, armpits and the area around the anus, are susceptible to the formation of stretch marks in the local treatment with BELOSALIC, therefore use of the ointment on these areas should be maximally limited.
- In cases of fungal superinfection of skin lesions, consult a doctor in order to additionally apply the appropriate medicine.
- It should be remembered that a long-term local therapy could cause development of microorganisms resistant to aminoglycosides.
- If you develop an infection with microorganisms, consult a doctor in order to apply the appropriate treatment.

Taking other medicines

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

There are no clinically relevant interactions with other medicines.

Simultaneous use of cosmetic or dermatological preparations for acne and those containing ethanol, medical soaps with a strong drying effect, and other may in certain cases increase skin irritations.

Children

Due to larger skin surface to total body weight ratio and under-developed stratum corneum, increased absorption of betamethasone and salicylic acid may occur in children during topical application. This may lead to manifestation of systemic toxicity. The preparation should not be used under the diapers because these garments (especially those made of plastic) work like occlusive dressing and increase absorption. Consequently, this preparation should be administered to children with great caution and for the shortest period of time possible.

Patients with hepatic insufficiency, and patients requiring long-term topical application

Patients with hepatic insufficiency, and patients requiring long-term topical application of BELOSALIC ointment or ointment, especially if occlusive dressings are indispensable, should be carefully monitored because, due to increased absorption of betamethasone, systemic manifestations may occur.

Pregnancy and breastfeeding

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

BELOSALIC in pregnant and nursing women should be used only when necessary.

Driving and using machines

There is no evidence that BELOSALIC ointment has effect on the ability to drive and use machines.

3. HOW TO TAKE BELOSALIC

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

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

It should be applied to the affected area in a thin layer on the skin. It should be applied twice a day. Wash your hands after using this medicine.

The treatment should not exceed 3 weeks. In the chronic skin conditions, to prevent relapses, treatment should continue for some time even after the disappearance of all symptoms, under constant supervision of a physician. In the case of longer administration, use the medicine less frequently, eg every other day.

If you take more BELOSALIC than you should

Never apply more BELOSALIC ointment than you are prescribed.

If you have applied more BELOSALIC than you should or over a longer period than you were prescribed, immediately talk to your doctor or pharmacist.

If you forget to take BELOSALIC

If you forgot to apply BELOSALIC ointment do it as soon as possible and then continue as usual. Do not apply double dose to make up for a forgotten dose.

If you have accidentally swallowed ointment BELOSALIC

If you or someone else have accidentally swallowed BELOSALIC ointment, tell your doctor immediately.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, BELOSALIC can cause side effects, although not everybody gets them.

Topical administration of betamethasone may reduce collagen content in the subcutaneous tissue and cause atrophic changes in the skin, irreversible striae, ecchymoses, telangiectasia, folliculitis, hypertrichosis and allergic contact dermatitis. Prolonged therapy may lead to development of rash, pruritus, local hyperpigmentation or depigmentation of the skin, depigmentation of the hair, and inhibition of sebaceous glands function. Secondary skin infections may occur due to depression of immunity system. Systemic side effects of topical administration of betamethasone are due to absorption of the drug into circulation. They occur very rarely, in most cases upon overdose and usually withdraw immediately upon discontinuation of treatment. Topical application of salicylic acid may cause dermatitis.

Children, patients with hepatic insufficiency, and patients requiring long-term topical application of BELOSALIC ointment, especially if occlusive dressings are indispensable, should be carefully monitored because, due to increased absorption of betamethasone, systemic manifestations may occur.

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.

5. HOW TO STORE BELOSALIC

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use BELOSALIC after the expiry date which is stated on the label.

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 BELOSALIC contains

The active substances are betamethasone in the form of betamethasone dipropionate and salicylic acid in the form of gentamycin sulphate.

One gram of ointment contains 0.5 mg of betamethasone in the form betamethasone dipropionate and 30 mg of salicylate acid.

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

What BELOSALIC looks like and contents of the pack

White, translucent, homogeneous ointment.

30 g of ointment in an aluminum tube with a plastic cap in a box.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Manufacturer

BELUPO Pharmaceuticals and Cosmetics

Ulica Danica 5

48000 Koprivnica Croatia

Manufacturer of the medicinal product

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