PACKAGE LEAFLET: INFORMATION FOR THE USER

BELOGENT

(0,5 + 1,0) mg/g ointment

BETAMETHASONE, GENTAMICIN

• 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 BELOGENT IS AND WHAT IT IS USED FOR

BELOGENT ointment contains Betamethasone is a glucocorticoid steroid from the group of strong corticosteroids. Gentamicin, the other active ingredient of this medicine is an antibiotic gentamicin used for the treatment of bacterial infections caused by microorganisms sensitive to gentamicin.
BELOGENT ointment is used for skin diseases which respond to topical treatment with corticosteroids, such as psoriasis, dermatitis, eczema, seborrhea and other changes on the skin, that are complicated by secondary infection caused by microorganisms sensitive to gentamicin.

2. BEFORE YOU TAKE BELOGENT

Do not take BELOGENT

- 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 BELOGENT, so you must tell the doctor if you

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

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

• Do not use BELOGENT 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 BELOGENT 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 BELOGENT, 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 with gentamicin could cause development of microorganisms resistant to aminoglycosides.

• Topical administration is not recommended in immunocompromised patients or other high-risk groups of patients. If during treatment resistance or superinfection develops, administration of gentamicin should be discontinued and appropriate treatment applied.

• If you develop an infection with microorganisms resistant to gentamicin, 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 gentamicin 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 BELOGENT 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.

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

Driving and using machines

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

3. HOW TO TAKE BELOGENT

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

BELOGENT ointment is suitable for the treatment of chronic dermatoses, such as dry, scaly lesions and lichens, in cases where the protective effect of the ointment is required. The required amount of BELOGENT ointment is

applied to the affected skin in a thin layer and gently rubbed in twice daily. On parts of skin with thick stratum corneum and on which the preparation is easily removed (e.g. palms and soles of the feet) treatment should be repeated more frequently.
Wash your hands after using this medicine, unless you are applying it on your hands.

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.

If you take more BELOGENT than you should

Never apply more BELOGENT ointment than you are prescribed.
If you have applied more BELOGENT than you should or over a longer period than you were prescribed, immediately talk to your doctor or pharmacist.

If you forget to take BELOGENT

If you forgot to apply BELOGENT 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 BELOGENT

If you or someone else have accidentally swallowed BELOGENT ointment, tell your doctor immediately.
Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, BELOGENT 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. Local reactions to gentamicin are usually manifested as hypersensitivity skin reactions characterized by rash, pruritus, erythema, swelling and other signs of irritation that have not existed before the therapy was started.

Children, patients with hepatic insufficiency, and patients requiring long-term topical application of Belogent ointment or 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 BELOGENT

Keep out of the reach and sight of children.

Do not store above 25 ºC.

Do not use BELOGENT 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 BELOGENT contains

The active substances are betamethasone in the form of betamethasone dipropionate and gentamicin in the form of gentamycin sulphate.
One gram of ointment contains 0.5 mg of betamethasone in the form betamethasone dipropionate and 1 mg gentamicin in the form of gentamycin sulphate.

Other ingredients: paraffin, liquid; Vaseline, white.

What BELOGENT looks like and contents of the pack

White, translucent, homogenous ointment.
15 g of ointment in an aluminum tube with a plastic cap, in a box.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Manufactuer
BELUPO Pharmaceuticals and Cosmetics
Ulica Danica 5
48000 Koprivnica Croatia

Manufacturer of the medicinal product
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