PACKAGE LEAFLET: INFORMATION FOR THE USER

BEPANTHEN PLUS

Cream 50 mg / g + 5 mg / g

DEXPANTHENOL, CHLORHEXIDINE

• 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 BEPANTHEN PLUS IS AND WHAT IT IS USED FOR

BEPANTHEN PLUS cream 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.
BEPANTHEN PLUS cream 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 BEPANTHEN PLUS

Do not take BEPANTHEN PLUS

- 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 BEPANTHEN PLUS, so you must tell the doctor if you

• If upon the first application of BEPANTHEN PLUS cream or ointment hypersensitivity reaction occurs on the skin (itching, burning, redness), administration should be immediately discontinued. BEPANTHEN PLUS cream should not be used under occlusive dressing, except if necessary. Prolonged use of BEPANTHEN PLUS cream on the face is not recommended due to possible occurrence of rosacea-like dermatitis, perioral dermatitis and acne.
• Do not use BEPANTHEN PLUS 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 BEPANTHEN PLUS cream 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 BEPANTHEN PLUS, therefore use of the cream 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 BEPANTHEN PLUS cream 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.
BEPANTHEN PLUS in pregnant and nursing women should be used only when necessary.

Driving and using machines
There is no evidence that BEPANTHEN PLUS cream and ointment have effect on the ability to drive and use machines.

Important information about some of the ingredients in BEPANTHEN PLUS

This medicine contains other substances chlorocresol and cetyl and stearyl alcohol. In local application, chlorocresol can cause an allergic reaction, and cetyl and stearyl alcohol may cause local skin reaction (atopic dermatitis).

3. HOW TO TAKE BEPANTHEN PLUS

When applying BEPANTHEN PLUS cream strictly follow the instructions given to you by your doctor.
BEPANTHEN PLUS cream is for topical application only. The cream is used in the therapy of acute moist skin lesions. The required amount of BEPANTHEN PLUS cream 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 BEPANTHEN PLUS than you should

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

If you forget to take BEPANTHEN PLUS

If you forgot to apply BEPANTHEN PLUS cream 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 cream BEPANTHEN PLUS

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, BEPANTHEN PLUS 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 Bepanthen Plus cream 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 BEPANTHEN PLUS

Keep out of the reach and sight of children.

Do not store above 25 ºC.

Do not use BEPANTHEN PLUS 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 BEPANTHEN PLUS contains

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

Other ingredients: chlorcresol, sodium dihydrogen phosphate monohydrate, phosphoric acid, macrogol cetostearyl ether, cetostearyl alcohol, liquid paraffin, white soft paraffin, sodium hydroxide and purified water.

What BEPANTHEN PLUS looks like and contents of the pack

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

Supplier and Manufacturer

Regime of dispensing
The medicine is issued on prescription.

Manufactuer

BELUPO Pharmaceuticals and Cosmetics
Ulica Danica 5
48000 Koprivnica Croatia

Manufacturer of the medicinal product

BELUPO Pharmaceuticals and Cosmetics
Ulica Danica 5
48000 Koprivnica Croatia

Marketing authorization holder

FARMAVITA d.o.o. Sarajevo
Igmanska 5a, 71320 Vogošća, Bosna i Hercegovina

Date and number of licenses for the marketing authorization

04-07.2-5034/11 date: 28.11.2011