

PACKAGE LEAFLET: INFORMATION FOR THE USER

BELODERM

0.5 mg/g, solution

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 solution is and what it is used for
2. Before you take Beloderm solution
3. How to take Beloderm solution
4. Possible side effects
5. How to store Beloderm solution
6. Further information

1. WHAT BELODERM SOLUTION IS AND WHAT IT IS USED FOR

The active substance of BELODERM solution is betametazondipropionat.

BELODERM solution belongs to the Group of medicines called topical corticosteroids. These medicines are applied to the surface of the skin to reduce the redness and itching caused by some skin diseases.

BELODERM solution is used in the treatment of dermatosis that respond to corticosteroids, and that includes all types of eczema and Dermatitis (skin inflammation), and psoriasis.

2. BEFORE YOU TAKE BELODERM SOLUTION

Do not use BELODERM:

- if you are hypersensitive to any of the ingredients of the medicinal product
- if you suffer from rosacea (a skin disease that affects the face, it manifests itself as reddening of the skin), acne, dermatitis around the mouth, itching in the area of the genitals, diaper rash, herpes in the area of the nose and lips, chickenpox, shingles, or other skin infections.
- if you are pregnant or breast-feeding. In this case, tell your doctor or pharmacist before you start taking BELODERM.

Be careful with the BELODERM solution

If used according to directions, BELODERM solution is well tolerated by most people. In case of excessive use you may experience hair thinning and the occurrence of the red stains. It more often occurs in children and infants.

Do not use BELODERM solution below the bandages, and in the area near the eyes.

If you are not sure if any of the above applies to you, please contact your doctor.

Taking other medicines with BELODERM solution

Tell your doctor about all the medicines you are taking or have recently taken, including those that you bought without a prescription. If you are admitted to the hospital, inform responsible doctor that you use Beloderm, as well as about any other medicines you are taking.

There are no known interactions of Beloderm solution with other medicines

Pregnancy and breastfeeding

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

Tell your doctor as soon as possible if you are pregnant or think you are pregnant. Do not take this medicine if you are pregnant unless you have previously talked about it with your doctor. The application of BELODERM solution in pregnant women is allowed only in cases where the benefit to the mother is greater than the possible risk to the fetus.

It is not known if BELODERM solution is excreted into breast milk.

3. HOW TO TAKE BELODERM SOLUTION

It is important that you apply medicine as determined by your doctor. If you are not sure how to use this medicine, ask your doctor or pharmacist for advice.

In children and adults, the recommended dose is a few drops twice a day onto the affected area. Your doctor may prescribe a different drug administration and in this case, follow your doctor's instructions.

Beloderm solution is intended for topical application.

Do not use the medication in the folds (e.g., groin, armpit) due to the higher risk of local and systemic toxicity.

Do not use the solution under bandages due to the increased absorption of the medicine, and more frequent side effects.

Children

Children are more susceptible to the adverse effects of systemic administration of equal dose due to the larger surface of the skin in relation to body mass.

If BELODERM solution is applied in children, treatment should not last longer than 5 days. Do not use Beloderm solution in children under 12 years of age, except on the recommendation of a doctor.

How long can you use BELODERM solution?

Do not use a larger quantity of solution for a longer period of time (for example, every day for several weeks or months).

If you have mistakenly swallowed BELODERM solution

If you or someone else accidentally swallows the solution, the appearance of side effects should not occur. However, if you are concerned, call your doctor.

If you have applied more BELODERM solution than you should

If you apply the solution to the skin more often than recommended, it can disrupt the balance and secretion of some hormones. If you have not followed the instructions about dosage, or advice of your doctor and you have used the solution too often and/or during an extended period of time, tell your doctor or pharmacist.

If you forget to use BELODERM solution

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 any further questions on the use of BELODERM, contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines BELODERM may cause side effects.

If used according to the recommended instructions about dosage, BELODERM does not cause difficulties. However, if you use a solution too often, this can cause thinning of the skin and red spots, especially in infants and children.

The following local side effects have been reported when using Beloderm solution:

burning, itching, irritation, dryness, folliculitis (inflammation of the hair follicle), hypertrichosis (increased hairiness), acneiform eruptions (change on the face like acne), hypopigmentation, perioral dermatitis (redness and inflammation around the mouth), allergic contact dermatitis (redness, swelling and blisters on the skin), skin maceration (inflammation and skin moisture), secondary infection, stretch marks, milia (disorder of sweat glands).

Long-term administration without interruption can cause local skin atrophy (a condition of the skin), stretch marks and superficial vascular dilatation, especially on the face (vasodilatation).

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

5. HOW TO STORE BELODERM SOLUTION

Keep BELODERM solution out of reach and sight of children.

Store at a temperature below 25 °C.

The expiry date is 2 years.

BELODERM solution must not be used after the expiry date which is stated on the carton.

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 solution contains

The active substance is betamethasone.

One gram of solution contains 0.5 mg betamethasone in the form of betamethazondipropionat.

Other ingredients: isopropyl alcohol; carbomer; sodium hydroxide; water, purified.

What BELODERM solution looks like and contents of the pack

Colorless, clear to slightly turbid viscous solution.

20 mL of solution in white polyethylene bottle with yellow polyethylene cap, in a box.

Regime of dispensing

The medicine is issued on doctor's prescription.

Manufacturer

Belupo Ijekovi i kozmetika d.d.

Danica 5, Koprivnica, Croatia

Manufacturer of the medicinal product

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