

PACKAGE LEAFLET: Information for the patient

BETAVAL

Cream – 0.1%

(Betamethasone valerate)

Read this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

1. What Betaval is and what it is used for
2. Before you use Betaval
3. How to use Betaval
4. Possible side effects
5. How to store Betaval
6. Further information

1. WHAT BETAVAL IS AND WHAT IT IS USED FOR

Betaval contains the active substance betamethasone valerate. Betamethasone valerate is a glucocorticoid with strong anti-inflammatory and immunosuppressor properties. Betamethasone valerate is absorbed in small quantities by the skin.

Application of large amounts of cream will increase its concentration in blood in significant levels.

It is indicated in severe inflammatory diseases of the skin (eczema, psoriasis) that have not responded to treatment with less potent corticoids.

Your doctor may have prescribed Betaval for another purpose. Talk to your doctor if you want to

know why Betaval was prescribed to you.

2. BEFORE YOU USE BETAVAL

Do not use Betaval:

- if you are hypersensitive to betamethasone valerate;
- if you are hypersensitive to any of the excipients listed at the end of this package leaflet;
- in infants under one year of age;
- in skin tuberculosis;
- in syphilis;
- if you have viral skin infections;
- if you have skin infections caused by fungi;
- if you have skin reactions caused by vaccine;
- if you have ulcers, dermatitis, rosacea or peribuccal dermatitis.

If you think you suffered any of the above-mentioned situations, do not use the cream, inform your doctor and follow up the given medical advice.

Take special care with Betaval

The use of the cream in children of a small age must be done only in special cases.

In areas such as face, genital areas or hairy areas, the cream should be used carefully, in small areas and not longer than a week. In case of use for long time and in large quantities, the patient must control the production of endogenous corticoids.

Inform your doctor if:

- the child treated is at a young age;
- you are allergic to other drugs, particularly if they are in the same therapeutic class with Betaval;
- you are pregnant or are planning to become pregnant while you are using Betaval;
- you are breastfeeding your baby or are planning to breastfeed.

Taking other medicines

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicine, especially if you are taking ritonavir and itraconazole medications because they may increase the effect of Betaval.

Pregnancy and breastfeeding

Inform your doctor or pharmacist if you are pregnant or if you are planning to become pregnant, if you breastfeed your baby or are planning to breastfeed because Betaval is contraindicated in this period.

Your doctor or pharmacist will inform you about the risks and benefits of using it.

Driving and using machines

Be careful while driving or using machinery until you see how Betaval affects you. However, there are no known effects on the psychophysical ability to drive or use machinery.

Important information about some of the excipients of Betaval

This medicine contains methyl hydroxybenzoate and propyl hydroxybenzoate which may cause allergic reactions (possibly delayed).

3. HOW TO USE BETAVAL

Apply the cream once or twice daily to the affected skin area.

Always use Betaval exactly as your doctor has told you. If you feel that Betaval effects are very strong or too weak, talk to your doctor or pharmacist.

Your doctor may advise you to use Betaval for a long time.

You should check with your doctor or pharmacist if you are not sure.

If you use more Betaval

If you use more Betaval than you should, or if the children use it by mistake, please contact your doctor.

If you forget to use Betaval

If you forget to apply Betaval, apply the next dose at its usual time.

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

If you have any further question on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

All medicines might cause side effects. Sometimes they are serious, mostly they are not. Do not get worried from this list of possible side effects. No one of them might appear to you.

Inform your doctor if any of the below-listed side effects disturbs you:

- local effects such as: skin irritation, burning, itching or dry skin;
- a prolonged use of the cream could feature local corticoid typical reactions such as: skin atrophy, contact dermatitis, folliculitis, hypertrichosis, irritation and drying of the skin, perioral dermatitis, hypopigmentation;
- during application over large areas, especially in damaged skin or when it is covered with coatings that isolate it from the environment, systemic effects of betamethasone can be seen.

If you notice any side effect not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE BETAVAL

Keep out of the sight and reach of children.

Do not use Betaval after the expiration date stated on the packaging.

Store below 25°C.

6. FURTHER INFORMATION

What Betaval contains

The active substance is betamethasone valerate.

1 g cream contains 1 mg betamethasone (as betamethasone valerate).

The excipients are:

Macrogol stearate, macrogol glycerol oleate, liquid paraffin, methyl hydroxybenzoate, propyl hydroxybenzoate, essence rose, diethanolamine, ethanol, purified water.

Content of the pack

Carton box with 1 tube of 15 g.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in November 2023.