

Package leaflet: Information for the user

BetazonTrio 0.5 mg/g+10 mg/g+1 mg/g ointment

Betamethasone / Clotrimazole / Gentamicin

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

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1. What BetazonTrio is and what it is used for

BetazonTrio ointment is a combined medicinal product intended for use on skin. The corticosteroid contained in the product, betamethasone, reduces redness, swelling, relieves itching due to its pronounced anti-inflammatory and anti-allergic effects.

The antibiotic gentamicin effectively destroys a large number of micro-organisms that cause infections in humans, including infections of the skin.

Clotrimazole has pronounced antifungal activity.

BetazonTrio ointment is used in adults and children over 3 years for the treatment of a variety of skin inflammations (dermatitis and eczema), suitable for corticosteroid therapy, where an infection has developed, presenting with redness, irritation and worsening of the condition.

2. What you need to know before you use BetazonTrio

Do not use BetazonTrio:

- if you are allergic to betamethasone, clotrimazole, gentamicin or any of the other ingredients of this medicine (listed in section 6);
- if you have certain skin infections, such as herpes simplex or herpes zoster, varicella (chickenpox), skin syphilis, acne;
- if you suffer from skin irritation and redness around the mouth or have itching in the genitals and anus.

The product should not be used in children aged less than 3 years.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using BetazonTrio.

You should know that **prolonged use**:

- of highly active corticosteroids may lead to skin thinning and dilatation of superficial blood vessels in the treated area, especially when the medicine is applied on the skin of the face;
- of topical corticosteroids, the use of high doses or treatment of large skin areas may lead to significant corticosteroid penetration through the skin into the blood and to inhibition of the activity of adrenal glands. These events are more common in young children. Hypercorticism (see section 4 Possible side effects), growth retardation, delayed weight gain and increased intracranial pressure may develop.
- of topical antibiotics, including gentamicin and clotrimazole, may lead to the development of resistant microorganisms and susceptibility to additional infection. In these cases, the treatment with the product should be discontinued and appropriate therapy with another antibacterial product should be administered.
- may lead to chronification of existing psoriasis, development of resistance to therapy and worsening of the condition.

The product should be discontinued if redness, irritation, itching, swelling occur, as these could be signs of an allergy or a secondary infection.

The medicine should not be applied:

- in the eye or in its vicinity, since entering into the eye can result in glaucoma (elevated intraocular pressure).
- on open wounds or broken skin.

The use of an occlusive dressing facilitates corticosteroid penetration through the skin and favours the development of infection.

The medicine should be used in children and adolescents only in the absence of other treatment options.

Other medicines and BetazonTrio

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

There is no evidence of unfavourable interactions with other medicines.

BetazonTrio with food, drink and alcohol

There is no evidence of a need for a special diet or restrictions on certain types of foods and beverages during the treatment with this medicine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

The results of animal studies have shown evidence of harm to the foetus and the newborn after administration of betamethasone and clotrimazole.

The product should not be administered to pregnant women.

Breast-feeding

The product should not be administered to breast-feeding women or if it is required for the mother, breast-feeding should be discontinued.

Driving and using machines

BetazonTrio has no influence on the performance of activities requiring alertness, such as driving or using machines.

3. How to use BetazonTrio

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Depending on your complaints, the doctor will determine the appropriate dose for the treatment of your disease and the duration of treatment.

The recommended dose is:

Adults

A small amount of the product is applied twice daily on the affected skin.

Children and adolescents

Side effects, associated with the use of the product, are more common in children; therefore, it should only be used under the exact instructions of the physician.

Elderly

No dose adjustment is required in the elderly.

Method of administration

The product is applied in a thin layer, possibly through a gentle massage. The smallest amount of the ointment should be used, sufficient to achieve an effect.

After applying the medicine, wash your hands thoroughly. Thus, you will avoid possible entering of even small amounts of the ointment in the eyes.

If there is no improvement after a 3-4 week treatment, your doctor will decide whether you should continue the treatment with this product.

If you use more BetazonTrio than you should

If you have accidentally used more than the prescribed dose, contact your doctor or pharmacist. Do not use the medicine more often or for a longer period than that specified, in order to avoid overdosing.

If you forget to use BetazonTrio

Do not use more than the amount needed to make up for a missed application. Apply your usual dose as soon as you remember and continue the treatment as usual.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

The following side effects may occur with the use of the product:

Immune system disorders

Redness, itching, irritation, rashes, inflammation of the skin.

Endocrine disorders

Rarely, hypercorticism (increased production of hormones from the adrenal glands) may occur, manifesting with rounding of the face, obesity in the chest and abdomen, red-purple skin striations, easy bruising of the blood vessels, muscle weakness. In some cases, diabetes, increased blood pressure, increased bone fragility (osteoporosis), menstruation disturbances, excessive hair growth, acne may develop.

Vascular disorders

Dilatation of the superficial skin blood vessels.

Skin and subcutaneous tissue disorders

Burning and itching at the site of application.

In rare cases, skin thinning, striations, especially with the use of occlusive dressings and application in the region of skin folds, reduction and discolouration of the skin, excessive hair growth, skin inflammation, paleness, moisturising and softening of the skin, worsening of psoriasis, additional infections may occur.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. How to store BetazonTrio

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

After first opening of the pack, you can use this medicine for 28 days.

Do not use this medicine if you notice changes in the appearance of the ointment.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What BetazonTrio contains

- The active substances in 1 g ointment are betamethasone dipropionate, equivalent to betamethasone of 0.500 mg, clotrimazole of 10.0 mg, gentamicin sulphate, equivalent to gentamicin of 1.0 mg.
- The other ingredients (excipients) are paraffin, liquid and paraffin, white soft.

What BetazonTrio looks like and contents of the pack

BetazonTrio is a white to off-white ointment of uniform consistency, without air bubbles.

15 g BetazonTrio ointment in lacquered aluminum tubes, closed with a plastic screw cap and fitted with a latex ring at the bottom of the tube.

One tube with a patient information leaflet is inserted in a carton.

Marketing Authorisation Holder

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Manufacturer

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