

**Package leaflet: Information for the user**  
**BetazonTrio 0.500 mg/g + 10 mg/g + 1 mg/g cream**  
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**

1. What BetazonTrio is and what it is used for
2. What you need to know before you use BetazonTrio
3. How to use BetazonTrio
4. Possible side effects
5. How to store BetazonTrio
6. Contents of the pack and other information

**1. What BetazonTrio is and what it is used for**

BetazonTrio cream is a combined medicinal product, intended for cutaneous use. The corticosteroid betamethasone, contained in the product, diminishes redness, swelling and relieves itching because of its pronounced anti-inflammatory and anti-allergic effects. The antibiotic gentamicin destroys effectively a great number of microorganisms that cause infections in humans, including these of the skin. Clotrimazole itself exhibits a strong antifungal effect.

BetazonTrio cream is indicated for the treatment of various inflammations of the skin (dermatitides and eczemas) suitable for treatment with corticosteroids, where an infection, presented with redness, irritation and worsening of the condition, has developed.

## **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 a certain infection of the skin, such as herpes simplex or herpes zoster, varicella, cutaneous syphilis, acne;
- if you suffer from inflammation of the skin and redness around the mouth or experience itching in the region of genitalia and the anus.

The product should not be used in children below 3 years of age.

### **Warnings and precautions**

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

You should be aware that the long-term administration of:

- highly active corticosteroids may result in thinning of the skin and widening of the superficial blood vessels in the treated areas, especially when the product is applied on the skin of the face;
- topical corticosteroids, high-dose use or treatment of large skin areas may result in significant corticosteroid penetration through the skin to the blood and inhibition of the adrenal activity. These manifestations are more common in young children. Hypercorticism (see "Possible side effects"), growth retardation, delayed weight gain and elevated pressure in the skull may develop.
- topical antibiotics, including gentamicin, may result in development of resistant microorganisms and susceptibility to added infection. In such cases, the treatment with the product should be discontinued and appropriate therapy with another antibacterial product should be initiated.

- during a long-term treatment of psoriasis, recurrence of the disease, development of resistance to therapy and worsening of the condition are possible.

In case of presented allergy or symptoms of a secondary infection (redness, irritation, itching, swelling), the use of the product should be discontinued.

The product should not be applied in or near the eyes, because its application in the eye may lead to glaucoma.

The product should not be applied on open wounds or skin with impaired integrity.

Use of tightly dressings facilitates corticosteroid penetration through the skin and favours development of an infection.

The product should be applied to children and adolescents only in the absence of an alternative therapy.

### **Other medicines and BetazonTrio**

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

There are no data of unfavourable interactions with other medicines.

### **BetazonTrio with food, drink and alcohol**

There are no data for the need to observe a special dietary regimen or restrictions of certain types of food and drink during the treatment with this product.

### **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

Observational study data in animals show evidence of foetal and neonatal damages with the use of betamethasone and clotrimazole.

The product should not be used in pregnant women.

### Breast-feeding

The product should not be used in breast-feeding women or if its use is required for the mother, breast-feeding should be discontinued.

### **Driving and using machines**

BetazonTrio has no influence on the performance of activities requiring close attention, 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, your doctor will determine the dose and duration of treatment required for curing your disease.

#### The usual dose in adults is:

A small amount of the product is applied two-three times daily on the affected skin.

The product is applied in a thin layer through gentle massage, if possible. The minimal amount possible should be used, sufficient for achieving an effect.

If your condition does not improve after a 3-4-week treatment, your doctor will decide whether you should continue the therapy with this product.

#### Children and adolescents

The side effects, related with the use of the product, are more common in children; therefore, it should be used only in accordance with the exact instructions of the physician.

#### Elderly

No dose adjustment is required in the elderly patients.

#### **If you use more BetazonTrio than you should**

If you have accidentally used once more than the dose prescribed, contact your doctor or pharmacist. Do not apply the medicine more frequently or for a longer time than the prescribed in order to avoid overdose.

### **If you forget to use BetazonTrio**

Do not use an amount greater than the required one to make up for a forgotten application. Apply the usual dose as soon as you remember and continue the treatment in the usual manner.

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.

During treatment with the product, the following side effects are likely to occur:

#### Immune system disorders

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

#### Endocrine system disorders

Rarely, hypercorticism (increased production of adrenal hormones) may develop, presented with moon face, obesity in the breast and abdominal areas, reddish-violet skin striae, vulnerability of the blood vessels, muscle weakness. In some cases: development of diabetes, elevated blood pressure, increased bone fragility (osteoporosis), disturbances in menstruation, excessive bodily terminal hair (hirsutism), acne.

#### Vascular disorders

Dilatation of the superficial blood vessels in the skin.

#### Skin and subcutaneous tissue disorders

Sensation of burning and itching at the site of administration.

In rarer cases, thinning of the skin, formation of striae, especially when using occlusive dressings and applying the medicine in areas of skin folds, discolouration (hypo- or hyper-pigmentation) of the skin, excessive bodily terminal hair (hirsutism), skin inflammation, paleness, humidification and softening of the skin, worsening of psoriasis, added infections are likely to 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 BatazonTrio**

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.

In-use period after first opening: 28 days.

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

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 cream contains**

- The active substances in 1 g of the cream 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 are benzyl alcohol; propylene glycol; sodium dihydrogen phosphate dihydrate; phosphoric acid, cetomacrogol 1000, cetostearyl alcohol; paraffin, liquid; paraffin, white soft (*Vaseline album*); purified water; sodium hydroxide.

### **What BetazonTrio looks like and contents of the pack**

BetazonTrio cream is a white, homogenous cream-like mass with no air bubbles.

It is supplied in 15 g containing aluminium, lacquered tubes closed with a plastic screw cap, with a latex ring at the lower end of the tube.

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

**Marketing Authorisation Holder**

Antibiotic-Razgrad AD  
Office 201, 68 “Aprilsko vastanie” Blvd  
Razgrad 7200, Bulgaria

**Manufacturer**

Balkanpharma-Razgrad AD  
68 “Aprilsko vastanie” Blvd  
Razgrad 7200, Bulgaria

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Antibiotic-Razgrad AD  
Office 201, 68 “Aprilsko vastanie” Blvd  
Razgrad 7200, Bulgaria  
Tel.: +359 (84) 613 318; fax: +359 (84) 634 272

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