

Package leaflet: Information for the patient

Bifonazol ABR 10 mg/g cream

bifonazole

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 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. See section 4.

What is in this leaflet

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

1. What Bifonazol ABR is and what it is used for

Bifonazole is a broad-spectrum imidazole derivative active against various fungal species, including dermatophytes, fungi, molds and other species, such as *Malassezia furfur*. It is also effective against *Corinebacterium minutissimum*.

Bifonazole ABR is used for the treatment of skin fungal diseases caused by infections with dermatophytes, fungi, molds and other fungi, incl. *Malassezia furfur* and *Corinebacterium minutissimum*: tinea pedum (fungus on the feet), tinea manum (fungus on the hands), tinea corporis (fungi on the body), tinea inguinalis (fungi in the creases of the groin), erythrasma.

2. What you need to know before you use Bifonazol ABR

Do not use Bifonazol ABR if:

- you are allergic to bifonazole or any of the other ingredients of this medicine (listed in section 6), for example if you are allergic to cetostearyl alcohol.

Warnings and precautions

Talk to your doctor or pharmacist before using Bifonazol ABR.

Children

No adverse effects have been identified in children. In infants, bifonazole should only be administered under medical supervision.

Other medicines and Bifonazol ABR

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

There are no known interactions with Bifonazole ABR cream.

Pregnancy

No harmful effects on mother and child have been demonstrated with bifonazole during pregnancy. There are no clinical safety data.
The product should not be administered without consulting your doctor during the first 3 months of pregnancy.

Driving and using machines

The product does not affect the ability to drive and use machines.

3. How to use Bifonazol ABR

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

The cream is used once a day, preferably in the evening before bedtime.
In order to achieve a lasting result, treatment with bifonazole containing cream should be complete and the cream should be applied for an appropriate period of time.

Usually the treatment periods are as follows:

Foot mycosis, athletic foot (tinea pedum, tinea pedum intradigitalis): 3 weeks

Mycoses of the body, hands and skin folds (tinea corporis, tinea manum, tinea inguinalis): 2-3 weeks

Pityriasis versicolor, erythrasma: 2 weeks

Superficial skin candidiasis: 2-4 weeks

A small amount of cream is usually sufficient to treat a skin area the size of a human palm.

Method of administration

The product should be applied as a thin layer on the affected skin and rubbed into it.

Duration of treatment

The duration of treatment will be determined by your doctor.

If you use more Bifonazol ABR than you should

There are no data of overdose.

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.

Very common side effects (may affect more than 1 in 10 people) are:

Nervous system disorders - pain

Skin and subcutaneous tissue disorders - contact dermatitis, eczema, persistent itching (pruritus), rash (vesiculobular), dry skin, unpleasant skin sensation.

Common side effects (may affect more than 1 in 100 people) are:

Immune system disorders - allergic reaction

These side effects are reversible upon discontinuation of treatment.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Bulgarian Drug Agency
8 Damyan Gruev Street
1303 Sofia

Tel. +359 28903417
Website: www.bda.bg

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bifonazol ABR

Store below 25°C.

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

Shelf life after first opening: 3 (three) months if stored below 25°C.

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.

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 Bifonazol ABR contains

- The active substance is bifonazole. 1 g cream contains 10 mg bifonazole.
- The other ingredients are: octyldodecanol, cetostearyl alcohol, cetyl wax, sorbitan stearate, polysorbate 60, benzyl alcohol, purified water.

What Bifonazol ABR looks like and contents of the pack

Description: homogeneous white mass, free of agglomerates and air bubbles.

Bifonazole ADB cream 15 g in aluminium tubes, lacquered, sealed with plastic screw cap, 1 tube with a package leaflet in a carton box

Bifonazole ADB cream 30 g in aluminium tubes, lacquered, sealed with plastic screw cap, 1 tube with a package leaflet in a carton box

Marketing Authorisation Holder

Antibiotic-Razgrad AD
68 Aprilsko Vastanie Blvd., office 201
7200 Razgrad, Bulgaria

Manufacturer

Antibiotic-Razgrad AD
68 Aprilsko Vastanie Blvd.
7200 Razgrad, Bulgaria

For additional information about this medicinal product, please contact the local representative of the Marketing Authorization Holder:

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