

Package leaflet: Information for the patient

Clotrimazol ABR 10 mg/g cream Clotrimazole

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.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 4 days.

What is in this leaflet

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

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

The name of your medicine is Clotrimazol ABR. It contains the active substance clotrimazole, which inhibits the development of various fungi and other microorganisms that cause common infections in humans.

Clotrimazol ABR cream is indicated for the topical treatment of:

- Infections of the skin and mucous membranes caused by fungi and some bacteria (dermatomycosis, erythrasma, pityriasis versicolor).
- Fungal infections of the labia and adjacent areas in women and the glans and foreskin (prepuce) of the penis in men (female thrush (candidal vulvitis), male thrush (candidal balanitis)).

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

Do not use Clotrimazol ABR, if you are allergic to clotrimazole or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Clotrimazol ABR.

During treatment with this medicine, you need to know the following:

- The cream should not be applied in close proximity to the eyes or be placed in them;
- The contents of the tube should not be swallowed;
- All infected skin areas should be treated simultaneously;
- If after 4-week administration the symptoms of your disease do not improve, you should consult your doctor.
- To achieve the expected therapeutic effect, the duration of administration of this medicine should be consistent with the information in section 3 or your doctor's instructions.
- This medicine can reduce the security of latex contraceptive products, such as condoms and diaphragms. Therefore, you should consult a specialist for alternative methods and means, designed to prevent pregnancy.

Other medicines and Clotrimazol ABR

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

When you apply the cream in the labial and adjacent areas, on the glans or foreskin of the penis, it is possible to reduce the safety of latex products, designed to prevent pregnancy (see section “Warnings and precautions”). The effect is temporary and occurs only during treatment with the 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 using this medicine.

If you are pregnant or attempting to become pregnant, you should not apply Clotrimazol ABR cream, except in cases where your doctor has decided that this is appropriate. This is especially true for the first trimester of pregnancy.

Breast-feeding should be discontinued during treatment with this medicine.

Driving and using machines

Clotrimazol ABR cream has no or negligible influence on the ability to drive and use machines.

Clotrimazol ABR contains cetostearyl alcohol

Cetostearyl alcohol may cause local skin reactions, such as contact dermatitis.

3. How to use Clotrimazol ABR

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

The affected area is treated 2-3 times daily, as a bar of the cream with length of about 0.5 cm is sufficient to treat an area with the size of a human palm. The cream is applied in a thin layer, as the required amount is rubbed gently on a clean and dry skin.

To achieve complete healing, the treatment should last as follows, depending on the type of infection:

Dermatomycosis	3 – 4 weeks
Erythrasma	2 – 3 weeks
Pityriasis versicolor	1 – 3 weeks
Candidal balanitis	1 – 2 weeks
Candidal vulvitis	1 – 2 weeks

If after treatment, conducted in accordance with the above instructions, there is no improvement or healing, you should ask your doctor for advice.

If you use more Clotrimazol ABR than you should

There are no reports of harmful effects in case of using a higher dose than recommended. In case you accidentally swallow the contents of the tube, ask your doctor for advice.

If you forget to use Clotrimazol ABR

Do not apply a double dose to make up for a forgotten dose. Apply the required amount of the cream as soon as you remember. If it is time for your next dose, continue your treatment as usual.

If you stop using Clotrimazol ABR

Do not stop applying your medicine too early, even when your condition is improving. In such cases, the symptoms of the disease may return, and thus you may help for the development of microorganisms resistant to the action of clotrimazole.

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.

Side effects, listed below, are based on reports from the post-marketing experience of clotrimazole-containing products for topical use, and therefore, correct estimate of their frequency is not possible.

Possible side effects during treatment with clotrimazole include:

Immune system disorders

Not known (cannot be estimated from the available data) – allergic reactions (impaired consciousness due to a sharp drop in the blood pressure, low blood pressure, shortness of breath, hives).

Skin and subcutaneous tissue disorders

Not known (cannot be estimated from the available data) – skin blisters, discomfort/pain, swelling, redness, irritation, flaking, itching, rash, stinging, burning.

If you get any of these side effects, you should stop your treatment with the product and ask your doctor for advice.

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” Str.
1303 Sofia
Tel.: +359 2 8903417
website: www.bda.bg

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

5. How to store Clotrimazol ABR

Keep this medicine out of the sight and reach of children.
Store in the original package.
Store below 25°C.

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

After first opening of the tube, you can use this medicine for 3 months. Store in the original package, in a place protected from direct sunlight, at a temperature below 25°C.

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 Clotrimazol ABR contains

- The active substance is clotrimazole.

- 1 g of the cream contains 10 mg of clotrimazole.
- The other ingredients (excipients) are octyldodecanol, cetostearyl alcohol, cetyl palmitate, sorbitan stearate, polysorbate 60, benzyl alcohol, purified water.

What Clotrimazol ABR looks like and contents of the pack

Clotrimazol ABR cream is white to off-white, homogenous, creamy mass without air bubbles.

The medicinal product is packed in 20 g lacquered aluminium tubes fitted with a membrane, closed with a plastic screw cap, with a latex ring at the lower end.

One tube with a package leaflet per carton box.

Marketing Authorisation Holder

Antibiotic-Razgrad AD
Office 201, 68, "Aprilsko vastanie" Blvd.
7200 Razgrad, Bulgaria

Manufacturer

Balkanpharma-Razgrad AD
68, "Aprilsko vastanie" Blvd.
7200 Razgrad, 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.
7200 Razgrad, Bulgaria
Tel.: +359 084 613 427
e-mail: office@antibiotic.bg

This leaflet was last revised in 01/2017.