

BIOTRIMAZOLE 10_{mg/gram} Cream

Clotrimazole

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without medical prescription. Nevertheless, you still need to use **Biotrimazole** carefully to get the best results from it

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.
- 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 **Biotrimazole** is and what it is used for
2. Before you use **Biotrimazole**
3. How to use **Biotrimazole**
4. Possible side effects
5. How to store **Biotrimazole**
6. Further information

1. What is Biotrimazole is and what it is used for

Biotrimazole is an antifungal medicine.

The cream is useful in the local treatment of the following conditions, in adults, elderly, adolescents and children over 5 years of age:

- Cutaneous mycoses caused by *Candida albicans*;
- Erythrasma;
- Dermatophytoses of skin and hair roots (*tinea corporis*, *tinea cruris*, *tinea pedis*, *tinea barbae*, *tinea capitis*) caused by *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Epidermophyton floccosum*, *Microsporum canis*;
- Pityriasis versicolor caused by *Malassezia furfur*;
- Paronychia associated to onychomycoses (fungal infection of nail adjacent tissues).

2. Before you use Biotrimazole

Do not use Biotrimazole:

- if you are allergic (hypersensitive) to clotrimazole or any of the other ingredients of the medicine;
- if the infection is located in the nails or scalp.

Take special care with Biotrimazole

This medicine is intended for the treatment of the skin.

Before application wash the affected area (preferably using alkaline soap) and dry it.

Do not apply the cream on the eye, nose and mouth area, mucous membranes or gaping wounds. If the cream touches the eyes accidentally, wash the affected area with a lot of clean water; if adverse reactions occur and persist, you need to ask your doctor.

For the healing of interdigital mycoses (athlete's foot), it is recommended to powder your socks or inside your shoes with talc or other absorbent powder.

Feet should be washed and dried very well, especially in the affected area.

If during treatment with **Biotrimazole** irritation phenomena at the application site or allergic reactions occur, discontinue the treatment and contact your doctor.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Clotrimazole cream decreases the efficacy of amphotericin and of other polyenic antibiotics (nystatin, natamycin).

If sprays or other cosmetics are used on the affected area, the reduction of clotrimazole efficacy cannot be excluded.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

No adequate controlled studies have been performed in pregnant women. The use of clotrimazole is not recommended during the first trimester of pregnancy.

In the second and third trimesters of pregnancy, clotrimazole will be used only if it is absolutely necessary, after your doctor's careful evaluation of the foetal potential risk/maternal therapeutic benefit ratio.

Because it is not known whether topical clotrimazole is excreted in human breast-milk, caution should be exercised when the cream is used by nursing women, only on medical advice.

Driving and using machines

Biotrimazole has no influence on the ability to drive or use machines.

Biotrimazole TM contains cetostearyl alcohol and benzyl alcohol.

May cause skin reactions (e.g. contact dermatitis, mild local irritation), as well as allergic reactions.

3. How to use Biotrimazole

Adults, elderly, adolescents and children over 5 years of age:

Biotrimazole is applied topically 2 to 3 times daily after washing and drying the affected area. Duration of treatment varies:

- generally 3 – 4 weeks in case of dermatomycoses caused by dermatophytes and *Candida*;
- 2 – 4 weeks in case of erythrasma;
- 1 – 3 weeks in case of pityriasis versicolor.

To prevent recurrence of disease, treatment of fungal infections will continue about 2 weeks after symptoms disappear.

The efficacy and safety of clotrimazole in children below 5 years of age have not been established.

If you use more Biotrimazole than you should

Remove the cream by washing the area. In the event of accidental oral ingestion or of an overdose call your doctor immediately or contact the Emergency Department of your nearest hospital.

If you forget to use Biotrimazole

If you forgot to use a dose, use it as soon as you remember. However, if it is time for the next dose, use just this one. Do not use a double dose to make up for a forgotten dose.

If you stop using Biotrimazole

If you stop using **Biotrimazole** earlier than is recommended, your condition may recur or may not improve.

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

4. Possible side effects

Like all medicines, **Biotrimazole** can cause side effects, although they do not occur in all persons.

Adverse reactions are classified according to the following frequencies:

Very common:	may affect more than 1 in 10 people.
Common:	may affect up to 1 in 10 people.
Uncommon:	may affect up to 1 in 100 people.
Rare:	may affect up to 1 in 1,000 people.
Very rare:	may affect up to 1 in 10,000 people.
Not known:	frequency cannot be estimated from the available data.

Immune system disorders:

–rare: allergic reactions (blisters, redness of skin, swelling, itching, stinging sensation, urticaria).

Skin and subcutaneous tissue disorders:

– rare: burning sensation, skin fissures, skin rash.

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

5. How to store Biotrimazole

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

Store in the original package, at temperatures below 25 °C.

Use within maximum 16 weeks after first opening of the tube.

Keep out of the sight and reach of children.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

6. Further information

What Biotrimazole contains

–The active substance is clotrimazole. One gram of cream contains clotrimazole 10 mg.

–The other ingredients are: octyldodecanol, cetostearyl alcohol, cetyl palmitate, sorbitan stearate, polysorbate 60, benzyl alcohol, purified water.

What Biotrimazole looks like and contents of the pack

Biotrimazole is a white to yellowish–white homogeneous cream.

Outer carton containing one tube of 15 g, 35 g, 20 g or 30 g cream.

The holder of trademark and Marketing Authorization is

“BioActiveT, United Kingdom.”

BioActiveT