Package leaflet: Information for the user

Binanidda 1% creme, creme 10 mg/g

terbinafine hydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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 1 to 2 weeks.

What is in this leaflet

1. What [Nationally completed name] is and what it is used for

- [Nationally completed name] belongs to the group of antifungal preparations. [Nationally completed name] is used to treat patients with fungal and yeast infections of the skin.

- [Nationally completed name] is active against certain yeasts and skin fungi, of which athlete's foot is the most well-known. See also section 3 for more information about the other fungal infections.

You must talk to your doctor, if you do not feel better or if you feel worse after 1 to 2 weeks.

2. What you need to know before you use [Nationally completed name]

Do not use [Nationally completed name]

- if you are allergic to terbinafine or any of the other ingredients of this medicine (listed in section 6). You can recognise hypersensitivity for example by red spots and lumps on the skin or itching.

Warnings and precautions
Talk to your doctor or pharmacist before using [Nationally completed name].

Terbinafine cream is for external use only. It may be irritating to the eyes. Contact with the eyes should be avoided. In case of accidental contact with the eyes, rinse eyes thoroughly with running water.

Children and adolescents
Take special care with [Nationally completed name] if you are under 12 years of age.
Terbinafine cream should be kept out of the reach of children.

Consult your doctor if one of the above warnings applies to you or has done so in the past.

Other medicines and [Nationally completed name]
Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.
There is no evidence that [Nationally completed name] has an effect on other products.

Pregnancy and breast-feeding

Pregnancy
You should not use [Nationally completed name] if you are pregnant or planning to get pregnant. If you get pregnant whilst using this medicine tell your doctor.
Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding
Because terbinafine passes into the breast milk, you should not use [Nationally completed name] during breast-feeding. Also infants must not be allowed to come into contact with any treated skin, including the breast. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Terbinafine cream has no influence on the ability to drive and use machines.

[Nationally completed name] contains cetyl alcohol and stearyl alcohol
May cause local skin reactions (e.g. contact dermatitis).

[Nationally completed name] contains benzyl alcohol
This medicine contains 10 mg benzyl alcohol per gram cream. Benzyl alcohol may cause allergic reactions and mild local irritation.

3. How to use [Nationally completed name]

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.

Kind of administration:
Cutaneous use

The opening of the tube is sealed with aluminium. You can break the seal with the inverted top of the tube, exerting slight pressure. Before applying the cream, the skin must be carefully washed and dried.

Smear a thin layer of cream on the inflamed skin and a little round about. Rub the cream in gently. If the inflammation is in a skin fold (under the breasts, between the toes or fingers, in the groin or between the buttocks) the skin can be covered with a sterile gauze, especially at night. Wash your hands after rubbing in, unless your hands are the area that is being treated.

Use in adults and adolescents *(*>12 years of age*)*
Duration and frequency of treatment
Athlete's foot (Tinea pedis): once a day for one week.

The symptoms that can be associated with athlete's foot are itching, redness and scaling between the toes and on the soles of the feet. Cracks sometimes also appear (particularly between the toes) and oozing blisters can occur as well. Athlete's foot usually produces an unpleasant odour.

Ringworm (tinea cruris and tinea corporis): once a day for one week.

Ringworm consists of slowly growing, itchy, red and scaling ring-shaped patches that can be dispersed over the body.

Skin fungus (cutaneous candidiasis): once a day for 1 to 2 weeks.

Candida is a species of yeast that can cause an infection of the skin in certain circumstances. Often the skin abnormalities are located in warm, damp areas such as the groin or under the breasts. The symptoms consist of itching, redness and scaling.

Pityriasis versicolor: 1 to 2 times a day for 2 weeks.

The yeast that causes pityriasis versicolor is Malassezia furfur. An infection with this yeast mainly occurs on the shoulders and the upper part of the trunk and upper arms. The symptoms consist of slightly itchy and slightly scaling patches. In people who are fairly sun-tanned, the patches are usually lighter than the rest of the skin, and in people who have been exposed to little or no sun, the spots are usually light brown.

An improvement in the symptoms usually occurs after a few days. Irregular use or premature stoppage of the cream increases the chance of the symptoms recurring. If no improvement has occurred after 1 to 2 weeks, contact your doctor or pharmacist.

Use in the elderly
There is no evidence that elderly patients require a different dose or will suffer different side effects from younger patients.

Use in children
There is only limited experience with the administration of [Nationally completed name] to the skin of children under 12 years of age and therefore use in this age group is not recommended.

If you use more [Nationally completed name] than you should
If you have used too much [Nationally completed name], this will not cause any harm, but contact your doctor or pharmacist if you are uncertain.
If someone, e.g. a child, swallows [Nationally completed name] accidentally, adverse effects similar to those observed with an overdose of tablets containing terbinafine (e.g. headache, nausea, bellyache and dizziness) are to be expected. In this case, contact your doctor or poison information centre.

In case of contact with the eyes, rinse eyes thoroughly with running water.

If you forget to use [Nationally completed name]
Continue the treatment without applying [Nationally completed name] an extra time or using it more than normal.

If you stop using [Nationally completed name]
If you suddenly stop using [Nationally completed name], the old symptoms can recur.

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.

Stop using the cream and seek medical help immediately if you have any of the following allergic reactions:
- severe itching of the skin, with a red rash or raised lumps, hives or blisters
- shortness of breath or swelling of the mouth, face, lips, tongue or throat

Other side effects:

Common (may affect up to 1 in 10 users)
- peeling skin (exfoliation)

- itching of the skin (pruritus)

Uncommon (may affect up to 1 in 100 users)
- pigmentation disorder
- pain and skin irritation at the application site
- skin lesion, scab
- redness of the skin (erythema)
- burning of the skin

Rare (may affect up to 1 in 1,000 users)
- eye irritation
- dry, flaky skin
- worsening of your underlying fungal infection

If you suffer badly from the side effects mentioned, it is advisable to consult your doctor.

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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Nationally completed name]

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 label and carton after "EXP". The expiry date refers to last day of that month.

Store in the original package.
Do not freeze.
Keep the tube tightly closed.

You can use [nationally completed name] 3 months after first opening of the tube.

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 [Nationally completed name] contains

- The active substance is terbinafine hydrochloride. One gram of cream contains 10 mg terbinafine hydrochloride.
- The other ingredients are sodium hydroxide (E524), benzyl alcohol, sorbitan stearate (E491), cetyl palmitate, cetyl alcohol, cetostearyl alcohol, polysorbate 60 (E435), isopropyl myristate, purified water.

What [Nationally completed name] looks like and contents of the pack

[Nationally completed name] is presented in the form of a cream. The contents of the aluminium tube with a polyethylene screw cap are 7.5, 15 and 30 grams.

The cream is white or almost white.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Ratiopharm GmbH
Graf-Arco-Str.3
89079 Ulm
Duitsland

Manufacturer
Merckle GmbH
Ludwig-Merckle-Str. 3
89143 Blaubeuren
Duitsland

In het register ingeschreven onder
RVG 33313

This medicinal product is authorised in the Member States of the EEA under the following names:

Binnnida NL/H/0748/001

Netherlands	Binanidda 1% creme
Norway	Terbinafin ratiopharm 10 mg/g krem
Portugal	Silbiter
Sweden	Terbinafin Teva 10 mg/g kräm
Germany	Fungizid-ratiopharm® Extra
Latvia	Terbinafin-ratiopharm 10 mg/g krēms
Lithuania	Terbinafin-ratiopharm 10 mg/g, kremas

Deze bijsluiter is voor het laatste goedgekeurd in mei 2021