

Terbinafine Hydrochloride

VITER08-1 (PHIL)

Terbivid

10 mg/g (1% w/w) Cream
Antifungal

Description

White to almost white homogenous cream free from grittiness.

Composition

Terbinafine hydrochloride 1% w/w

Actions and Pharmacology

Terbinafine is an allylamine which has a broad spectrum of antifungal activity in fungal infections of the skin. It's action being fungicidal against dermatophytes, moulds and certain dimorphous fungi. It has a fungicidal or fungistatic action on yeasts depending on the species involved. Terbinafine interferes with fungal ergosterol biosynthesis at an early stage. This leads to a deficiency in ergosterol and to intracellular accumulation of squalene, resulting in fungal cell death.

Terbinafine acts by inhibiting squalene epoxidase in the fungal cell membrane. The squalene epoxidase is not dependent on the cytochrome P450 system. Terbinafine does not have any influence on the metabolism of hormones or of other medicines.

Pharmacokinetics

Less than 5% of the dose is absorbed after topical application in humans; systemic exposure is thus very slight. Biotransformation results in metabolites with no antifungal activity, which is excreted predominantly in the urine and the faeces. The elimination half life is 17 hours. There is no evidence of accumulation. At the level of the stratum corneum, fungicidal concentrations of terbinafine can be measured up to 7 days after the last administration.

Indications

For the topical treatment of:

- Fungal infections of the skin caused by *Trichophyton* (e.g. *T. Rubrum*, *T. Mentagrophytes*, *T. Verrucosum*, *T. Violaceum*), *Microsporum canis* and *Epidermophyton floccosum*.
- Yeast infection of the skin, principally those caused by the genus *Candida* (e.g. *C. albicans*).
- Pityriasis (tinea) versicolor due to *Pityrosporum orbiculare* (also known as *Malassezia furfur*).

Contraindications

Hypersensitivity to terbinafine or to one of the adjuvants contained in the cream.

Warnings and Precautions

- For external use only.
- Contact with the eyes should be avoided.

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

- In the event of skin lesions, use with care if the preparation contains alcohol which can irritate.

Effects on Ability to Drive and Use Machines

Unlikely to impair a patient's ability to drive or use machinery.

Pregnancy and Lactation

There is no clinical experience in pregnant women; therefore, unless the potential benefits outweigh any potential risks, it should not be administered during pregnancy.

Terbinafine is excreted in breast milk and although the amount involved is small, mothers should not receive it whilst breast-feeding. Infants should also not be allowed to come into contact with any treated skin, including the breast.

Interaction with Other Medicaments

None known.

Main Side/Adverse Effects

Erythema (redness), pruritus (itching) or stinging (burning sensation) occasionally occurs at the site of application; however, treatment rarely has to be discontinued for this reason.

This must be distinguished from allergic reactions which are very rare but require discontinuation.

Overdose and Treatment

No case of overdosage has been reported so far. However, should a large amount of the preparation be inadvertently ingested, adverse effects similar to those observed with an overdosage of a tablet form of terbinafine are to be expected. These include headache, nausea, vomiting, epigastric pain and dizziness.

In case of accidental oral ingestion, gastric lavage and / or symptomatic supportive treatment should be performed as soon as possible.

Dosage and Administration

Adults and children from 12 years:
Cleanse and dry the affected areas thoroughly before application.

Apply a thin layer on the affected skin and surrounding areas by rubbing in gently.

Cream can be applied once or twice daily. The likely durations of treatment are as follows:

Tinea corporis, cruris: 1 to 2 weeks

Tinea pedis: Toes, twice daily for 1 week, on the bottom or sides of the foot for 2 weeks

Cutaneous candidiasis: 2 weeks

Pityriasis versicolor: 2 weeks

In cases of intertriginous infections (submammary, interdigital, intergluteal, inguinal), a gauze can be used, especially for applications in the evening.

Relief of clinical symptoms usually occurs within a few days. Regular application is essential for successful treatment. Irregular use or premature discontinuation of treatment carries the risk of recurrence. If there are no signs of improvement after one week, the diagnosis should be verified.

Children

The experience with topical terbinafine in children is still limited and its use cannot therefore be recommended.

Use in the elderly

There is no evidence to suggest that elderly patients require different dosages or experience side-effects different to those of younger patients.

Note : The information given here is limited. For further information consult your doctor or pharmacist.

Storage:

Store at temperatures not exceeding 30°C. Protect from freezing.

Availability:

Aluminum tube x 15g, Box of 1's

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

Seek medical attention immediately at the first sign of any adverse drug reaction

Registration Number: DRP-10284

Date of First Authorization:
03 September 2021

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Antifungal

WHAT IS IN THIS LEAFLET

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WHAT TERBIVID IS USED FOR

Terbivid is used to treat the topical fungal infections below:

- athlete's foot (tinea pedis) – especially when it occurs between the toes
- dhotie (jock) itch (tinea cruris) – itchy rash with a clear border which often occurs on the groin and inner thigh area.
- ringworm (tinea corporis) – circular patches of red rash which may appear scaly
- skin candidiasis (intertrigo or sweat rash) – redness, itching and scaling in folded areas of skin which are wet with perspiration.
- pityriasis (tinea) versicolor – scaly patches that become white areas due to loss of skin pigmentation.

Terbivid is an antifungal and works by killing the fungi causing your skin problem.

BEFORE YOU USE TERBIVID

When you must not use it

- Do NOT use in children under 12 years of age.
- Do NOT use to treat fungal nail infection (inside and under the nail), with discoloration of the nails and change in nail texture (thick, flaky). Please see your doctor for appropriate treatment for this type of infection

- Do NOT use Terbivid:

- If you are allergic (hypersensitive) to terbinafine hydrochloride or any of the other ingredients of this medicine (listed in Product Description).

Important information about some of the ingredients of Terbivid

Terbivid contains

- cetyl alcohol and stearyl alcohol: may cause local skin reactions (e.g. contact dermatitis).

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Should not be used during pregnancy unless clearly necessary.

Do not use Terbivid while breast-feeding. Do not allow infants to come into contact with any treated areas, including the breasts. The ingredients can pass into your breast milk.

Before you start to use it

Talk to your doctor or pharmacist before using Terbivid.

- It is for external use only.
- Do not use it in the mouth or swallow it.
- Keep the cream away from your eyes. If the cream accidentally gets into your eyes, rinse the eye thoroughly with running water. See your doctor if you are still in any discomfort.

Taking other medicines

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

Do not apply other medicinal products on the areas being treated.

HOW TO USE TERBIVID

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.

It is important to use Terbivid correctly. Follow the instructions carefully.

Directions for use:

Adults and adolescents aged 12 years and over:

- Clean and dry the affected skin and surrounding areas, and wash your hands.
- Unscrew the cap, and if using for the first time, use the point in the cap to pierce the top of the tube, then gently squeeze the tube.
- Apply enough cream to put a thin layer on the affected skin and surrounding areas.
- Rub in gently.
- Replace the cap on the tube.
- Wash your hands after touching the infected skin so that you do not spread the infection on yourself or to others.

If you are treating an infection in folded areas of your body you can cover the treated area with a gauze strip, especially at night. If you do, use a fresh, clean gauze strip each time you apply the cream.

If applied to face, keep away from your eyes.

How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

When to use Terbivid

- Athlete's foot: apply once a day.
- Dhotie (jock) itch and ringworm: apply once a day.
- Skin candidiasis (intertrigo or sweat rash): apply once or twice a day.
- Pityriasis versicolor: apply once or twice a day.

How long to use Terbivid

Apply Terbivid to the infected areas as follows:

- Athlete's foot: apply for one week.
- Dhotie (jock) itch and ringworm: apply for one week.
- Skin candidiasis (intertrigo or sweat rash): apply for one to two weeks. This may look like ringworm or dhotie itch but it occurs in elderly or obese patients with moist areas of overlapping folds of skin, or those with other conditions such as diabetes. The longer treatment duration (2 weeks) may be needed to treat candidiasis.
- Pityriasis versicolor: apply for two weeks.

Use the cream for the recommended treatment period even if the infection seems to be better after a few days. Infections usually appear to improve within a few days, but may reappear if the cream is not applied regularly or is stopped too early.

Terbivid should start to improve your skin condition in a few days. Terbivid will continue to work even after you have completed the treatment.

If you have not noticed any signs of improvement within 2 weeks of first starting treatment, please see your doctor or pharmacist who will advise you.

To help with the treatment

To help with the treatment keep the affected area clean by washing it regularly. Dry it carefully without rubbing, but dabbing it gently. Try not to scratch the area although it may be itchy, because this could cause further damage and slow the healing process or spread the infection.

Because these infections can be passed on to other people, remember to keep your own towel and clothes and do not share them with others. To protect yourself from re-infection these should be washed frequently.

If you forget to use Terbivid

If you forget an application of the cream, apply it as soon as possible and then carry on as normal. If you only remember at the time of the next application, just apply the usual amount and then carry on as normal.

Do not apply a double dose to make up for a forgotten dose.

Try to use the cream as indicated. This is important to get the best results and prevent the infection from returning.

If you use too much of Terbivid (overdose)

Symptoms/signs of overdose following ingestion of terbinafine may include headache, nausea, epigastric pain and dizziness.

If you or someone else accidentally swallows some Terbivid, please tell your doctor who will advise you on what to do.

WHILE YOU ARE USING IT

Things you must do

Take your medicine exactly as your doctor has told you.

Patient Information Leaflet

Things you must not do

- It is for external use only.
- Do not use it in the mouth or swallow it.
- Avoid contact of the cream with your eyes. If the cream accidentally gets into your eyes, rinse thoroughly with running water. If any discomfort persists, see your doctor.

Things to be careful of

Driving and using machines

Terbivid has no influence on the ability to drive and use machines.

SIDE EFFECTS

Like all medicines, Terbivid can cause side effects, although not everybody gets them.

Most people benefit from using Terbivid.

STOP using Terbivid and seek medical help immediately if you have any of the following which may be signs of an allergic reaction:

- difficulty in breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps

The following side effects have been reported:

Skin problems such as skin peeling, itching, skin lesion, scab, skin disorder, skin color changes, redness, burning, pain, application site pain, application site irritation.

Other side effects include:

Dry skin, eczema, contact dermatitis which is a type of inflammation of the skin, skin rash, worsening of disease symptoms, allergic reactions.

Be aware that in rare cases the underlying fungal infection may be aggravated.

If Terbivid is accidentally applied to the eyes, eye irritation may occur.

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

For suspected adverse drug reaction, report to the FDA: www.fda.gov/ph

Seek medical attention immediately at the first sign of any adverse drug reaction

STORAGE AND DISPOSAL OF TERBIVID

Storage

- Keep this medicine out of the reach and sight of children.
- Do not store at temperatures exceeding 30°C.
- Do not use Terbivid after the expiry date which is stated on the package. The expiry date refers to the last day of that month.
- Keep the tube closed and in the carton.
- Store in the original package.

Disposal

- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer used. These measures will help to protect the environment.

PRODUCT DESCRIPTION

What it looks like?

The cream is white to almost white and free from grittiness in aluminum tube.

Ingredients

Active ingredients

Terbinafine hydrochloride

Inactive ingredients

Purified water, sodium hydroxide, benzyl alcohol, sorbitan monooleate, cetyl palmitate, cetyl alcohol, stearyl alcohol, polysorbate 60, isopropyl myristate.

Registration Number

DRP-10284

MANUFACTURER

HOVID Bhd.

121, Jalan Tunku Abdul Rahman
(Jalan Kuala Kangsar), 30010 Ipoh, Perak, Malaysia.

PRODUCT REGISTRATION HOLDER

HOVID Bhd.

121, Jalan Tunku Abdul Rahman
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IMPORTED AND DISTRIBUTED BY

HOVID Inc.

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33 Shaw Boulevard, Pasig City, 1600 Philippines.

DATE OF FIRST AUTHORIZATION / RENEWAL OF AUTHORIZATION

03 September 2021

DATE OF REVISION

October 2021