accord

Package leaflet: Information for the user

Terbinafine 250mg tablets

Read all of this leaflet carefully before you start taking 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 Terbinafine tablets are and what they are used for

Terbinafine belongs to a group of medicines called antifungal drugs. Terbinafine tablets are used for the treatment of fungal infections of:
- The groin area.
- The skin (ring worm).
- Toe and finger nails (yellow, opaque and thickened nails).
- The feet (athlete's foot).

2 What you need to know before you take Terbinafine tablets

Do not take Terbinafine tablets if you:
- are **allergic** to terbinafine or any of the other ingredients of this medicine (listed in section 6).
- have or have had any **liver** problems.
- are **breast-feeding**.

Warnings and precautions
Talk to your doctor or pharmacist before taking Terbinafine tablets if you:
- are **pregnant** or trying to become pregnant.
- have any problems with your **kidneys** or **liver**.
- have **psoriasis** (scaling skin disease)
- have **systemic lupus erythematosus (SLE)** (auto-immune disorder, affecting the skin, joints, kidneys & brain), as it may worsen whilst you are taking Terbinafine tablets.
- have a **rash** due to a high level of a specific type of white blood cells.

Children and adolescents
Use in children is not recommended.

Other medicines and Terbinafine tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is especially important to tell your doctor about the following:
- Rifampicin (an antibiotic).
- Cimetidine (used to treat stomach ulcers).
- Antidepressants including tricyclic antidepressants, SSRIs (selective serotonin reuptake inhibitors) or MAOIs (monoamine oxidase inhibitors) (medicines for depression).
- Oral contraceptives (as irregular periods and breakthrough bleeding may occur in some female patients).
- Beta blockers or antiarrhythmics (for heart problems).
- Warfarin, a medicine used to thin your blood.
- Medicines to treat heart problems (eg propafenone, amiodarone).
- Ciclosporin (a medicine used to control your body's immune system in order to prevent rejection of transplanted organs).
- Medicines used to treat fungal infections (e.g. fluconazole, ketoconazole)
- Medicines used to treat cough (e.g. dextromethorphan)
- Caffeine

You should have blood tests before and during treatment with Terbinafine tablets to monitor your liver function.

Pregnancy and breast-feeding
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 taking this medicine

If you are breast-feeding, you should not take Terbinafine tablets. If you are pregnant or planning to become pregnant, you should not take Terbinafine tablets unless your doctor decides it is necessary. You must only take Terbinafine tablets according to your doctor's instructions.

Driving and using machines
Some people have reported feeling dizzy or giddy while they are taking Terbinafine tablets. If you feel like this you should not drive or operate machinery.

3 How to take Terbinafine tablets

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

Swallow the tablets **with water**.

The usual dose for adults, including the elderly, is 250 mg once a day.
- For skin infections continue taking the tablets for 2 to 6 weeks.
- For nail infections treatment usually lasts for between 6 weeks and 3 months, although some patients with toenail infections may need to be treated for 6 months or longer.
- If your kidneys are not working very well, your doctor may reduce the dose of Terbinafine tablets you take.
- Swallow the tablets whole with a glass of water.

Complete healing of the infection may not occur until several weeks after completing the course of treatment. A healthy nail may take several months to grow back.

If you take more Terbinafine tablets than you should
If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include headache, feeling sick, pain in the upper part of the stomach (epigastric pain) and dizziness.

If you forget to take Terbinafine tablets
Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time.

4 Possible side effects

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

Some side effects can be serious
Stop taking the tablets and tell your doctor immediately if you notice any of the following rare symptoms:
- Yellowing of your skin or eyes. Unusually dark urine or pale faeces, unexplained persistent nausea, stomach problems, loss of appetite or unusual tiredness or weakness (this may indicate liver problems), increase in liver enzymes which may be noted on a blood test result
- Severe skin reactions including rash, light sensitivity, blistering or wheals
- Weakness, unusual bleeding, bruising, abnormal pale skin, unusual tiredness, or weakness or breathlessness on exertion or frequent infections (this may be a sign of blood disorders)
- Difficulty breathing, dizziness, swelling mainly of the face and throat, flushing, crampy abdominal pain, stiffness, rash, fever or swollen/enlarged lymph nodes (possible signs of severe allergic reactions)
- Symptoms such as rash, fever, itching, tiredness or if you notice appearance of purplish spots under the skin surface (signs of blood vessel inflammation)
- Severe upper stomach pain which spreads to the back (possible signs of pancreas inflammation)
- Unexplained muscle weakness or pain, or dark (red-brown) urine (possible signs of muscle breakdown)

Other side effects
Tell your doctor if you notice any of the following side effects or any other effects not listed:

Very common (may affect more than 1 in 10 people)
- Stomach problems such as loss of appetite, ache, indigestion, feeling bloated or sick
- Diarrhoea
- Itching, rash or swelling
- Pains in the muscles and joints

Common (may affect up to 1 in 10 people)
- Headache

Uncommon (may affect up to 1 in 100 people)
- Taste loss and taste disturbance. This usually disappears within several weeks after you stop taking the medicine. However, a very small number of people, (less than 1 in 10,000), have reported that the taste disturbance lasts for some time and, as a result, they go off their food and lose weight.There have also been reports of some people experiencing anxiety or symptoms of depression as a result of these taste disturbances.

Rare (may affect up to 1 in 1,000 people)
- Feeling unwell, dizzy
- Numbness or tingling

Very rare (may affect up to 1 in 10,000 people)
- Feeling tired
- Decrease in the number of some blood cells. You may notice that you seem to bleed or bruise more easily than normal, or you may catch infections easily and these might be more severe than usual
- Psoriasis like skin eruptions, or worsening of any psoriasis including a rash or eruption of small pus containing blisters
- Vertigo
- Hair loss
- Onset or worsening of a condition called lupus (a long-term illness with symptoms including skin rash and pain in the muscles and joints)

Not known (frequency cannot be estimated from the available data)
- Signs of blood disorders: weakness, unusual bleeding, bruising or frequent infections
- Anxiety and depressive symptoms.
- Disorders of sense of smell which may be permanent, impaired hearing, hissing and/or ringing in the ears, flu like symptoms, increase in blood of a muscle enzyme called creatine phosphokinase (may be found on a blood test), reduced or blurred vision.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Terbinafine tablets

Keep this medicine out of the sight and reach of children.
This medicine does not require any special storage conditions.
Do not use this medicine after the expiry date which is stated on the label/carton/bottle. 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 require. These measures will help protect the environment.

6 Contents of the pack and other information

What Terbinafine tablets contain
- The active substance is terbinafine as terbinafine hydrochloride. Each tablet contains 250mg of the active substance.
- The other ingredients are microcrystalline cellulose, croscarmellose sodium, anhydrous colloidal silica, hypromellose and magnesium stearate.

What Terbinafine tablets look like and contents of the pack
Terbinafine tablets are white, round, flat tablets, scored on both sides with side scores and marked with 'T' above and '1' below the score on one side.
Pack sizes for blister packs: 7, 14, 20, 28, 30, 42, 50, 60, 84, 90, 98, 100, 50 x 1 (unit dose) tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Accord, Barnstaple, EX32 8NS, UK.

Manufacturer:
Actavis Ltd, BLB 015-016 Bulebel Industrial Estate, Zejtun ZTN 3000, Malta.

Accord Healthcare Limited
Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom.

Accord, Barnstaple, EX32 8NS, UK.

This leaflet was last revised in December 2020.

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Package leaflet: Information for the user

Terbinafine 1 % Cream
terbinafine hydrochloride

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.

In this leaflet:

1. What Terbinafine 1% Cream is and what it is used for

Terbinafine 1% Cream contains the active ingredient terbinafine hydrochloride which is an antifungal. It kills fungi, which cause skin infections. Terbinafine 1% cream is used for the local treatment of fungal infections of the skin only.

2. What you need to know before you use Terbinafine 1% Cream

Do not use Terbinafine 1% cream

- if you are allergic to terbinafine hydrochloride or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using Terbinafine 1% Cream.
This cream is for external use only.
Avoid contact with the eyes. If the cream gets in your eyes accidentally, rinse thoroughly with running water and tell your doctor immediately.

In the event of allergic reaction, the cream should be removed and the treatment interrupted.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Other medicines and Terbinafine 1% Cream
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding
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 taking this medicine.

If you are pregnant you should not use Terbinafine 1% cream unless it is clearly necessary and advised to by your doctor.
Do not use this cream if you are breast-feeding as terbinafine hydrochloride can pass into breast milk. Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Terbinafine 1% cream should not affect your ability to drive or operate machines.

Terbinafine 1% cream contains benzyl alcohol, cetyl alcohol and cetostearyl alcohol
This medicine contains 10 mg benzyl alcohol in each gram of cream. Benzyl alcohol may cause allergic reactions and mild local irritation. This medicine also contains cetyl alcohol and cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

3. HOW TO USE TERBINAFINE 1% CREAM

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

Adults (including older people)

Terbinafine 1% Cream may be applied 1-2 times daily. The recommended duration and frequency of treatment will depend upon the type and area of infection:

Tinea pedis (Athlete's foot): 1 week.
Tinea cruris (dhobie itch/jock itch) and Tinea corporis: 1-2 weeks.
Cutaneous Candida: 2 weeks.
Pityriasis versicolor: 2 weeks.

Infections usually appear to improve within a few days of starting to use the cream. It is important that you use the cream regularly even if the infection has improved. If you see no improvement in your skin condition after 2 weeks, talk to your doctor.

Directions for use

- Cleanse and dry the affected areas thoroughly and wash your hands. Treatment can be helped by keeping the affected areas clean by regular washing and careful drying with your own clean towels and clothes, and not rubbing or scratching the skin.
- Unscrew the cap then gently squeeze out a small amount of the cream onto your finger.
- Apply just enough cream to form a thin layer on the affected skin and surrounding areas.
- Rub in gently. When used between the toes, buttocks or on the groin, the treated area may be covered with a light, fresh gauze strip, especially at night.
- Replace the cap on the tube and wash your hands.

Even though you will not be using Terbinafine 1% Cream during the second week for Athlete's foot, full skin healing after the infection has cleared will continue for up to 4 weeks. If you have not noticed any signs of improvement within 2 weeks of first starting treatment, please seek advice from your doctor or pharmacist.

Use in children

Terbinafine 1% Cream is not recommended for children under 12 years.

If you use more Terbinafine 1% Cream than you should

Remove some of the cream if you apply more than a thin layer.
If you or someone else swallows the cream, go to your doctor or nearest hospital emergency department immediately. Take any remaining medicine and this leaflet with you if possible. Symptoms of accidental ingestion include headache, nausea (feeling sick), dizziness and stomach pain. If the cream gets in your eyes, rinse thoroughly with running water and tell your doctor immediately.

If you forget to use Terbinafine 1% cream

If you forget to use the cream, apply it as soon as you remember. If it is time for the next application, carry on as normal. It is important to try to remember to use the cream or you risk the infection returning.

If you stop using Terbinafine 1% cream

Do not stop using Terbinafine 1% cream before the recommended time, as the infection will be more likely to return.

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 very rare allergic reactions:

Not known (cannot be estimated from the available data):
- difficulty breathing or swallowing, swelling of the mouth, face, lips, tongue or throat (severe allergic reaction).
- severe itching of the skin, with a red rash or raised lumps, hives or blisters.

Other side effects

Common (may affect up to 1 in 10 people):
- skin peeling, itching.

Uncommon (may affect up to 1 in 100 people):
- skin lesions, scab, skin colour changes, redness, burning, pain and irritation at the site of application.

These effects are harmless and usually you can continue with the treatment.

Rare (may affect up to 1 in 1,000 people):
- eye irritation, dry skin, contact dermatitis, eczema, worsening of symptoms.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Terbinafine 1% Cream

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

Do not use Terbinafine 1% cream after the expiry date stated on the label or carton after EXP. The expiry date refers to the last day of that month.

Store in the original container. Do not freeze. Keep the tube tightly closed.
Discard the tube 28 days after first opening the tube.

Do not throw away any medicine 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 Terbinafine 1% cream contains

- The active substance is terbinafine hydrochloride. One gram of cream contains 10 mg of terbinafine hydrochloride equivalent to 8.89 mg of terbinafine.
- The other ingredients are sodium hydroxide, benzyl alcohol, sorbitan monostearate, cetyl palmitate, cetyl alcohol, cetostearyl alcohol (see section 2 "Terbinafine 1% Cream contains cetyl alcohol and cetostearyl alcohol"), polysorbate, isopropyl myristate and purified water.

What Terbinafine 1% cream looks like and the contents of the pack

Terbinafine 1% Cream is a white or almost white cream with a slight almond odour contained in aluminium tubes of, 7.5 g, 15 g or 30 g. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturer

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Gedeon Richter Plc., Gyömrői út 19-21, Budapest
H-1103, HUNGARY

This leaflet was last revised in 04/2019

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

Belgium	**Terbinafine Mylan 1 % crème**
France	**Terbinafine 1% Mylan, crème**
Germany	**Terbisil 10 mg/g Creme**
Norway	**Dermatomyl 1 % krem**
The Netherlands	**Terbinafine Mylan 10 mg/g, creme**
United Kingdom	**Terbinafine 1% cream**