Package leaflet: Information for the user

Terbasil 250 mg Tablets
Terbinafine (as Terbinafine Hydrochloride)

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, please ask your doctor or your 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 Terbasil Tablets are and what they are used for**
2. **What you need to know before you use Terbasil Tablets**
3. **How to use Terbasil Tablets**
4. **Possible side effects**
5. **How to store Terbasil Tablets**
6. **Contents of the pack and other information**

1. What Terbasil Tablets are and what they are used for

Terbasil Tablets contain terbinafine which is an "anti-fungal" medicine. Terbasil Tablets are used in adults and older people for the treatment of infections such as:
- fungal infections of the skin and nails
- ringworm

Terbasil Tablets kills the fungus or stops it growing.

2. What you need to know before you use Terbasil Tablets

Do not use Terbasil Tablets:
- if you are **allergic** to terbinafine or any of the other ingredients of this medicine (listed in section 6).
- if you have or had any liver problems
- if you are breast-feeding
- if you are pregnant or trying to become pregnant.

Do not take Terbasil if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Terbasil.

Warnings and precautions

Talk to your doctor or pharmacist before using Terbasil Tablets if you:
- have or had any **liver problems.** If test of liver functionality shows an increase, then Terbasil Tablets should be discontinued immediately.

- have **kidney problems** consult your doctor before taking these Tablets.
- are taking any **other medications**.
- have experienced thickened patches of red/silver skin (psoriasis) or facial rash, joint pain, muscle disorder, fever (cutaneous and systemic lupus erythematosus). . Terbasil can make these problems worse. If you notice that skin rash occurs, stop taking Terbasil Tablets.
- have a blood clotting disorder called thrombotic thrombocytopenic purpura (TTP) has been reported with terbinafine. Stop treatment immediately and see a doctor or go to hospital straight away, if you notice any symptoms of TTP mentioned in section 4, possible side effects.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Terbasil.

Look out for side effects
Terbasil can cause some side effects that may require urgent medical treatment. They include problems with your liver, skin, muscles or blood. See "Stop taking Terbasil and see a doctor or go to a hospital straight away, if you notice any of the following side effects" at the beginning of the Section 4 for more information.

Children and adolescents
Terbasil Tablets can be used in adolescents and children aged 2 years and over. As the patient grows, the doctor will adjust the dose.
Terbasil Tablets are not recommended for use in children under 2 years of age since there is no experience in this age group.

Other medicines and Terbasil Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, oral contraceptives or herbal medicines. This is because Terbasil can affect the way some other medicines work. Also some other medicines can affect the way Terbasil works. In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- rifampicin (used to treat infection)
- cimetidine (used to treat stomach problems such as indigestion or stomach ulcers)
- ciclosporin (used to control your body's immune system after a transplant)
- anti-depressants including tricyclic anti-depressants such as desipramine, SSRIs (selective serotonin reuptake inhibitors), or MAOIs (monoamine oxidase inhibitors)oral contraceptives (as irregular periods and breakthrough bleeding may occur in some females)
- anti-fungals (used to treat fungal infections such as fluconazole or ketoconazole)
- beta-blockers or anti-arrhythmics (used to treat heart problems such as metoprolol, propafenone or amiodarone)
- dextromethorphan (used in some cough medicines)
- tolbutamine (used for diabetes)
- terfenadine (an antihistamine)

- triazolam (a sedative)
- digoxin (to treat heart problems)
- caffeine (used in some pain killers or cold remedies)

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Terbasil.

Terbasil Tablets with food and drink
Terbasil Tablets may be taken with or without food, (see section 3). Terbasil may increase the effects of caffeine in your drinks.

Terbasil and Sodium
This medicine contains less than 1 mmol sodium (23 mg) per Tablet, that is to say essentially 'sodium-free'.

Pregnancy and Breast-feeding
Do not use Terbasil Tablets if you are pregnant or if you are breast-feeding. You should not breast feed if you are taking Terbasil Tablets as small amounts may passes into breast milk.

If you are pregnant, planning to become pregnant or are breastfeeding, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
There should be no effect on the ability to drive and operate machinery. If you have experienced dizziness after taking Terbasil Tablets, then avoid driving or using any tools or machinery.

3. How to use Terbasil Tablets
Always use 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 recommended dose is:
- **Adults (including the elderly):**

Your doctor will decide what dose of Terbasil you should take. The dose will be on the pharmacist's label. Check the label carefully. It should tell you how many Tablets to take, and how often.

The recommended dose for adults and older people is 250 mg once a day. If your liver or kidneys are not working very well, your doctor may reduce the dose.

Duration of treatment depends on the type of fungal infection you have and the severity of the infection and what part of your body is affected.
- For skin infections continue taking the Tablets for 2 to 6 weeks.

- **Fungal infection of the groin area, skin and feet:** 250 mg (one Tablet) once a day for 2-4 weeks. Some cases of athlete's foot may require treatment for up to 6 weeks.
  Complete healing of the infection may not occur until several weeks after completing the course of treatment.
- **Fungal infection of the nails:**
  Fingernails: 250 mg (one Tablet) once a day for 6 weeks.
  Toenails: 250 mg (one Tablet) once a day for 12 weeks. Some cases may require treatment for up to 6 months

- **Children and adolescents:**
  There is no experience with Terbasil in children under 2 years of age (usually less than 12kg).
  The dosage in children above 2 years of age depends on the body weight:
  Children weighing 20 to 40 kg – 125 mg (half a 250mg Tablet) once daily
  Children weighing more than 40 kg – 250 mg (one 250mg Tablet) once daily.

- **Impaired kidney function:**
  If you have impaired kidney function, you may need to take a lower dose. Your doctor will tell you how much to take.

- **Impaired liver function:**
  Terbasil Tablets are not recommended in patients with chronic or active liver disease.

If you have the impression that the effect of Terbasil Tablets is too strong or too weak, talk to your doctor or pharmacist.

Taking this medicine
You should take Terbasil by mouth. Swallow the Tablets whole with a glass of water. Terbasil can be taken with or without food. The Tablet can be divided into equal doses.

Other ways to clear up your infection
There are other steps that you can take to help clear up your infection and make sure that it does not return. For example, keep the infected area dry and cool and change clothing that is in direct contact with the infected area daily.

If you use more Terbasil 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. Take your medicine pack with you so that people can see what you have taken. Symptoms of an overdose include headache, dizziness, pain in the upper part of the stomach (epigastric pain) and feeling or being sick.

If you forget to take Terbasil Tablets

If you miss taking a Terbasil Tablet, do not worry. Take it as soon as you remember, unless it is less than 4 hours before your next dose is due. In this case, wait and take your next Tablet at the usual time. Then carry on as normal until you have finished all the Tablets. Do not take a double dose to make up for a forgotten dose.

If you stop using Terbasil Tablets
It may be some weeks before you feel an improvement. Do not stop taking Terbasil Tablets because you feel better. It is important to take the Tablets for as long as the doctor has told you to, otherwise the problem might come back.

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

If you notice any of the following serious side effects, stop using Terbasil Tablets and contact your doctor immediately – you may need urgent medical treatment:

- **impaired liver function or liver failure** including reduction in liver enzymes (seen in tests), yellowing of the skin or whites of the eyes (jaundice), inflammation of the liver (hepatitis) and blocked bile flow (cholestasis). Symptoms include itching, unexplained feeling of sickness, loss of appetite, unusual tiredness or weakness, being sick, fatigue, stomach pain, unusually dark urine or pale stools
- **a severe allergic (hypersensitivity) reaction** the signs may include swelling of the face, lips, tongue or throat, difficulty breathing or swallowing (anaphylaxis, flushing, stomach cramps or joint pain, stiffness, rash or swollen lymph glands. You may also become unconscious
- a sore throat with fever and shivering – signs that the medicine has affected your blood cells
- a sore throat, with fever, tiredness and ulcers appearing on your mouth or lips – signs of a problem with your immune system
- unusual bleeding or bruising – signs that the medicine has affected your blood cells
- stomach pain which spreads to your back – signs of "pancreatitis"
- unexplained muscle weakness and pain or having dark red-brown urine – signs of "muscle necrosis"
- feeling unusually tired, weak or breathless and looking pale – signs of "anaemia"
- onset or worsening of a condition called psoriasis (a long-term illness with symptoms including thickened patches of red and silver skin)
- onset or worsening of a condition called Lupus (a long-term illness with symptoms including fever, facial skin rash and pain in the muscles and joints)
- severe skin rash (including light sensitivity, swelling, blistering, scales or wheals)
- skin rash, fever, itching, feeling tired or if you notice purplish-reddish spots under your skin – signs that your blood vessels have become inflamed.

If you get any of the serious side effects listed above, stop taking Terbasil and see a doctor or go to hospital straight away.

Other side effects include
Talk to your doctor or pharmacist if you notice any of the following side effects:

Very common (may affect more than 1 in 10 people):
- stomach problems such as loss of appetite, stomach ache, indigestion, feeling bloated or sick
- diarrhoea
- headache
- skin rashes (itchy)
- joint pain and muscle pain

Common (may affect up to 1 in 10 people):

- feeling tired or dizzy
- depression
- disturbance or loss of sense of taste
- eye disorder

Uncommon (may affect up to 1 in 100 people):
If you notice unusually pale skin, nail beds or when you pull down your eyelids, feeling unusually tired, weak or breathless during physical activity (possible signs of a disease that affects the level of red blood cells), anxiety, tingling or numbness and decreased skin sensitivity, increased sensitivity of the skin to sun, noises (e.g. hissing) in ears, fever and weight loss.

Rare (may affect up to 1 in 1,000 people):
- yellow eyes or skin (liver problems) and abnormal liver function test results.

Very rare (may affect up to 1 in 10,000 people)

- numbness, tingling or loss of sensitivity to touch
- hair loss.

Not known (frequency cannot be estimated from the available data)
It is not known how often these happen
- loss of sense of smell or reduced ability to smell
- blurred vision, decreased sharpness of vision
- feeling anxious – signs include trouble sleeping, feeling tired, lack of energy, finding it difficult to think or concentrate
- feeling low in mood
- increase in blood level of a muscle enzyme – shown in blood tests
- skin rash due to high level of a specific type of white blood cells.
- fever accompanied by bruising under the skin that may appear as red pinpoint dots, with or without unexplained extreme tiredness, confusion, yellowing of the skin or eyes (jaundice) – signs of medical condition called thrombotic thrombocytopenic purpura (TTP).

If you develop a high fever or sore throat please contact your doctor who may wish to carry out some blood tests.

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 HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Terbasil Tablets

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 carton and Tablet blisters after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Terbasil Tablets contain:
The active substance is terbinafine (as terbinafine hydrochloride).
Each Tablet contains 250 mg terbinafine (as terbinafine hydrochloride).
The other ingredients are microcrystalline cellulose, croscarmellose sodium, hypromellose, magnesium stearate and colloidal anhydrous silica.

What Terbasil Tablets look like and the contents of the pack:
Terbasil Tablets are white, round, flat Tablets scored on both sides. On one side the Tablets are embossed “T” above and “1” below the score.

Terbasil 250 mg Tablets are available in packs of 28 Tablets.

Marketing Authorisation Holder
Accord Healthcare Ireland Ltd, Euro House, Euro Business Park, Little Island, Cork T45 K857, Ireland

Manufacturer
Actavis Ltd, BLB015-016 Bulebel Industrial Estate, Zejtun ZTN 3000, Malta.
Accord Healthcare Polska Sp. z o.o., ul. Lutomierska 50, Pabianice, 95-200, Poland
Accord Healthcare B.V., Winthontlaan 200, 3526KV Utrecht, The Netherlands

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