

**PROPOSED PATIENT INFORMATION LEAFLET (Clean copy)**

**SOUTH AFRICA:** S4

**NAMIBIA:** NS2

**BINACIL 125 mg (tablet)**

**BINACIL 250 mg (tablet)**

**Terbinafine**

**Read all of this leaflet carefully before you start taking this BINACIL.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **BINACIL** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**1. WHAT BINACIL CONTAINS**

The active substance is terbinafine.

**BINACIL 125 mg:** Each uncoated tablet contains terbinafine hydrochloride equivalent to terbinafine 125 mg.

**BINACIL 250 mg:** Each uncoated tablet contains terbinafine hydrochloride equivalent to terbinafine 250 mg.

The other ingredients are cellulose microcrystalline (Avicel PH-101), hypromellose, magnesium stearate, silica colloidal anhydrous and sodium starch glycolate.

**2. WHAT BINACIL IS USED FOR**

**BINACIL** may be used to treat:

- Fungal infections of the skin and nail such as athlete's foot, ringworm of the groin (jock itch) or ringworm of the body.

### **3. BEFORE YOU TAKE BINACIL**

#### **Do not take BINACIL:**

- If you have ever had an allergic reaction to terbinafine or any of the other ingredients found in **BINACIL**.
- If you have liver problems.
- If you are pregnant or breast-feeding.

#### **Take special care with BINACIL:**

- Check with your doctor at once if you develop any of the following symptoms of liver damage which usually occur within two months of starting treatment with **BINACIL**: itching, a feeling of sickness that won't go away (persistent nausea), loss of appetite, tiredness, yellowing of the whites of the eyes or skin, being sick (vomiting), fatigue, stomach/abdominal pain, dark urine or pale coloured stools.
- Before using **BINACIL**, tell your doctor:
  - if you have psoriasis – **BINACIL** may cause a worsening of psoriasis symptoms.
  - if you have kidney problems (see “**HOW TO TAKE BINACIL**”).

#### **Taking BINACIL with food:**

**BINACIL** may be taken with or without food.

#### **Pregnancy and Breastfeeding:**

- Do not take **BINACIL** if you are pregnant - Tell your doctor if you are pregnant or plan to become pregnant.
- Do not take **BINACIL** if you are breast-feeding, since **BINACIL** passes into breast milk.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking **BINACIL**.

#### **Driving and using machinery:**

**BINACIL** may make you feel dizzy or fatigued. Make sure you are not affected before you drive or operate machinery.

#### **Taking other medicines with BINACIL:**

Some medicines may interact with terbinafine. Before taking **BINACIL**, tell your doctor if you are using any of the following medicines:

- Rifampicin for tuberculosis because it may decrease the effectiveness of terbinafine.
- Cimetidine for indigestion or stomach ulcers, because it may increase the risk of side-effects when taken with terbinafine.
- Tricyclic antidepressants (e.g. amitriptyline),  $\beta$ -blockers (e.g. atenolol, metoprolol or propranolol), selective serotonin reuptake inhibitors (SSRIs) (e.g. fluoxetine) and monoamine oxidase type B (MAO-B) inhibitors (e.g. selegiline), because the risk of their side-effects may be increased by terbinafine.
- Oral contraceptives – as irregular periods and breakthrough bleeding may occur.
- Ciclosporin.
- Triazolam

Always tell your healthcare professional if you are taking any other medicine.  
(This includes complementary or traditional medicines.)

#### **4. HOW TO TAKE BINACIL**

Always take **BINACIL** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **BINACIL** is too strong or too weak, talk to your doctor or pharmacist.

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- The usual adult (including elderly) oral dose is 250 mg once a day.

- The length of your course of treatment will depend on the nature and severity of infection. Your doctor will tell you how long to take your medicine for.

Usual course lengths are as follows:

- For skin infections **BINACIL** is usually taken for between 2 to 6 weeks.
- For nail infections, treatment usually lasts between 6 weeks and 3 months, although some patients with toenail infections may need to be treated for 6 months or longer.

Signs of the infection may not disappear until several weeks after completing the course of treatment.

- To clear up your infection completely, take **BINACIL** for the full course of treatment.
- Children – The use of **BINACIL** in children is not recommended.
- Patients with kidney problems – Your doctor may prescribe a lower dose.

**If you take more BINACIL than you should:**

- If an overdose has been taken, there may be symptoms such as headache, feeling sick (nausea), pain in upper, middle region of stomach and dizziness.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

**If you forget to take BINACIL:**

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

**5. POSSIBLE SIDE EFFECTS:**

**BINACIL** can have side effects.

Get emergency medical help at once if you have any of these signs of an allergic reaction:

- hives, skin rash
- difficulty breathing
- swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have any of these serious side effects:

- Severe blistering, peeling and red skin rash
- Severe skin rash that keeps getting worse
- Unusual bruising or bleeding
- Fever, chills, sore throat, and other signs of infection
- Symptoms of liver problems (e.g. itching, a feeling of sickness that won't go away (persistent nausea), loss of appetite, tiredness, yellowing of the whites of the eyes or skin, being sick (vomiting), fatigue, stomach/abdominal pain, dark urine or pale coloured stools).

Other possible side effects are: nausea (queasiness); mild abdominal pain or fullness; diarrhoea; loss of taste or changes in taste (which usually resolves on discontinuation of the medicine); indigestion; headache; depression; anxiety; numbness, tingling or pins and needles; feeling unwell, tired or dizzy; oversensitivity to light; psoriasis (skin disease with raised, rough, scaly areas); pains in the muscles and joints, which may occur as part of an allergic reaction along with allergic skin reactions (rash, swelling).

Tell your doctor if any of the above side effects are severe, bothersome, do not go away or about any concerns you have while taking **BINACIL**.

Not all side effects reported for **BINACIL** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **CINACIL**, please consult your doctor, pharmacist or other health care professional for advice.

## **6. STORING AND DISPOSING OF BINACIL**

Store at or below 30 °C (room temperature).

**Store all medicines out of reach of children.**

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## **7. PRESENTATION OF BINACIL:**

### **BINACIL 125 mg:**

Tablets are packed in clear 250 microns PVC coated with 60 gsm PVdC and 25 microns printed Aluminium foil.

One blister contains 14 tablets.

**Pack size: 14's** - Each carton contains 1 blister of 14 tablets each

### **BINACIL 250 mg:**

Tablets are packed in clear 250 microns PVC coated with 60 gsm PVdC and 25 microns printed Aluminium foil. One blister contains 14 tablets.

**Pack size: 14's** - Each carton contains 1 blister of 14 tablets each.

## **8. IDENTIFICATION OF BINACIL:**

**BINACIL 125 mg:** White to off-white, round uncoated, biconvex bevelled edge tablets having 'D' debossed on one side and '56' on the other side.

**BINACIL 250 mg:** White to off-white, round uncoated, biconvex bevelled edge tablets with break line and 'D' debossed on one side and '74' on the other side.

## **9. REGISTRATION NUMBERS/REFERENCE NUMBERS**

### **SOUTH AFRICA:**

**BINACIL 125 mg:** 42/20.2.2/0471

**BINACIL 250 mg:** 42/20.2.2/0472

### **NAMIBIA:**

**BINACIL 125 mg:** 10/20.2.2/0261

**BINACIL 250 mg:** 10/20.2.2/0262

#### **10. NAME AND ADDRESS OF REGISTRATION HOLDER**

Aurogen South Africa (Pty) Ltd  
Woodhill Office Park, Building 1,  
53 Phillip Engelbrecht Avenue,  
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#### **11. DATE OF PUBLICATION**

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