PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.

- If you have further questions, please ask your doctor, pharmacist or health care professional.

- This medicine 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.

SCHEDULING STATUS:

S4

PROPRIETARY NAME (AND DOSAGE FORM):

MYLAN TERBINAFINE 250 MG (tablet)

WHAT MYLAN TERBINAFINE 250 MG CONTAINS:

The active substance is terbinafine hydrochloride equivalent to 250 mg terbinafine per tablet.

The other ingredients are: Colloidal silicone dioxide, Croscarmellose sodium, Magnesium stearate, Microcrystalline cellulose, Povidone, Talc.

The tablets are sugar-free.

WHAT MYLAN TERBINAFINE 250 MG IS USED FOR:

MYLAN TERBINAFINE 250 MG tablets are used to treat certain fungal infections of the skin (e.g. ringworm).

BEFORE YOU TAKE MYLAN TERBINAFINE 250 MG:

Do not take MYLAN TERBINAFINE 250 MG tablets:

- if you are hypersensitive (allergic) to terbinafine or any of the other ingredients of MYLAN TERBINAFINE 250 MG tablets
- if you have liver problems.

Pregnancy and Breast-feeding:

If you are pregnant while taking this medicine, please consult your doctor, pharmacist or health care professional for advice. Do not take this medicine if you are breastfeeding.

Taking MYLAN TERBINAFINE 250 MG with food:

MYLAN TERBINAFINE 250 MG is not affected by food.

Take special care with MYLAN TERBINAFINE 250 MG:

If you are taking the following medicines on a regular basis, including complementary or traditional medicines, the use of MYLAN TERBINAFINE 250 MG with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

Tell your doctor if you are taking: antidepressants, ciclosporin (immunosuppressant), cimetidine (stomach ulcers), oral contraceptives, rifampicin or rifabutin (antibiotics), terfenadine (antihistamine), tolbutamine, triazolam (sleeping tablet).

HOW TO TAKE MYLAN TERBINAFINE 250 MG:

Always take MYLAN TERBINAFINE 250 MG exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. The usual dose is:

Adults:

250 milligrams of MYLAN TERBINAFINE (one tablet) per day. The length of treatment will depend on the type of infection and the severity of the infection.

The period of treatment for skin infections is between 2 to 6 weeks.

The period of treatment for nail infections is usually between 6 weeks and 3 months, although it might take up to 6 months or longer.

It may take several weeks after treatment has been stopped for the signs and symptoms of the infection to disappear.

Children:

MYLAN TERBINAFINE 250 MG should not be used because of a lack of experience of use in children.

Patients with kidney problems:

If you have kidney problems, your doctor may change your dosage to a lower dose than stated above.

If you take more MYLAN TERBINAFINE 250 MG than you should:

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

If you forget to take MYLAN TERBINAFINE 250 MG:

If you forget to take a dose, take it as soon as you remember. Do not double the dose to make up for forgotten individual doses.

POSSIBLE SIDE-EFFECTS:

MYLAN TERBINAFINE 250 MG tablets have side-effects.

The estimated frequency is currently subdivided:

- very common ≥ 10 %, (more than 1 per 10);
- common > 1 % and < 10 %, (less than 1 per 10 but more than 1 per 100);
- uncommon 0,1 % to 1 %, (less than 1 per 100 but more than 1 per 1000);
- rare 0,01 % to 0,1 %, (less than 1 per 1000);
- very rare up to 0,01%, (less than 1 per 10,000).

Very common:

Side-effects that affect the stomach and intestines (e.g. indigestion, loss of appetite, feeling sick, stomach pain and watery, loose stools).

Other side-effects are skin rash, headache, pins and needles, dizziness, tiredness, pain in the joints or muscle and not feeling well.

If you notice any of the following side-effects, tell your doctor, pharmacist or health care professional: itchy skin or severe skin reactions, vomiting, looking pale,

yellowing of the skin or whites of the eyes, stomach cramps, tiredness, loss of appetite, pale stools or dark urine.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or health care professional for advice.

STORAGE AND DISPOSAL OF MYLAN TERBINAFINE 250 MG:

Store at room temperature (below 25 ^{0} C). Protect from light.

The blister strips must not be removed from the carton until required for use.

Do not use after the expiry date stated on the container.

Return all unused medicine to your pharmacist.

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

Keep all medicines out of the reach and sight of children.

PRESENTATION OF MYLAN TERBINAFINE 250 MG TABLETS:

White Securitainers: 14, 28 and 100 tablets.

PVC/Aluminium Blisters: 14 or 28 tablets.

IDENTIFICATION OF MYLAN TERBINAFINE 250 MG TABLETS:

White to almost white, round, biconvex tablets with “TF/250” on the one side and “G” on the other side.

REGISTRATION NUMBER:

A38/20.2.2/0691

NAME AND ADDRESS OF REGISTRATION HOLDER:

Xixia Pharmaceutical (Pty) Ltd

Building 6, Greenstone Hill Office Park

Emerald Boulevard

Modderfontein, 1645

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

8 October 2004