PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S1

Terbane® Nail (medicated nail lacquer)

terbinafine

Read all of this leaflet carefully because it contains important information for you:

TERBANE NAIL is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you need to use TERBANE NAIL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share TERBANE NAIL with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after a few days.

What is in this leaflet

1. What TERBANE NAIL is and what it is used for
2. What you need to know before you use TERBANE NAIL
3. How to use TERBANE NAIL
4. Possible side effects
5. How to store TERBANE NAIL
6. Contents of the pack and other information.

1. What TERBANE NAIL is and what it is used for

TERBANE NAIL contains the active substance terbinafine, which belongs to a group of medicines known as antifungals. It kills a wide variety of fungi that can cause nail infections.

TERBANE NAIL is used in adults to treat mild to moderate fungal infections of the nails.

You must talk to a doctor if your nails do not improve or get worse after 6 months for fingernails and 9 to 12 months for toenails.

2. What you need to know before you use TERBANE NAIL

Do not use TERBANE NAIL:

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

Warnings and precautions:

Take special care with TERBANE NAIL if:

- you have more than 3 nails affected, or the infection covers more than half of the nail surface or the part near the cuticle,
- you have diabetes,
- you have immune disorders,
- you have blood circulation disorder (peripheral vascular disease),
- you have injured, painful or seriously damaged nails,
- you have a skin condition (e.g. psoriasis),
- you have yellow nail syndrome (swelling in your legs, breathing problems and yellow nail discolouration).

TERBANE NAIL is for external use only.

Avoid contact with unaffected parts of the body until the lacquer is completely dry.
Accidental contact may cause irritation in the eyes or mucous membranes. In case of accidental contact with these areas, rinse thoroughly with running water.
Do not use nail polish or other cosmetic products that need to be applied on the nails and/or hands while you are using the treatment, as they may affect how TERBANE NAIL works.

Children and adolescents:

TERBANE NAIL should not be used in children or adolescents under the age of 18 years due to a lack of clinical studies in this age group.

Other medicines and TERBANE NAIL:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

If TERBANE NAIL is used as directed, very little terbinafine is absorbed into the body after application to the nail and so it is not likely that this could interfere with any other medicines that you are taking.

Do not use other medicines on the affected areas while you are using TERBANE NAIL.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using TERBANE NAIL.

Do not use TERBANE NAIL if you are pregnant or breastfeeding your baby. Please consult your doctor, pharmacist or other health care provider for advice.

This medicine can pass into your breastmilk. If you are breastfeeding, ask your doctor for advice before using this medicine.

Do not allow infants to come into contact with any treated areas. Make sure infants do not suck on your treated nails.

Driving and using machines:

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

3. How to use TERBANE NAIL

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

TERBANE NAIL is for use on fingernails or toenails.

Instructions for use:

Step 1: Before applying TERBANE NAIL, remove any nail polish or other cosmetic product from the nails and the skin right next to it.

Step 2: Clean and dry the affected areas thoroughly.

Step 3: Unscrew the bottle cap.

Step 4: Dip the applicator into the nail lacquer.

Step 5: Using the applicator, apply TERBANE NAIL in a thin layer over the entire surface of the affected nail, 5 mm of surrounding skin and, if possible, under the front nail edge as well as the skin under the nail.

Step 6: Wait about 30 seconds until the lacquer has completely dried before doing any activity.

Step 7: Close the bottle tightly.

The treated nails should not be washed or get wet for at least 6 hours. Therefore, application in the evening before going to bed and after showering or bathing is recommended. After that time, normal hygiene practices can be followed.

TERBANE NAIL does not need a special solvent to remove it. It can be removed easily by washing the nails with water. No filing down of the nail is required.

Duration of the treatment:

For the first 4 weeks, apply TERBANE NAIL to the affected nails once daily.

After that period, apply TERBANE NAIL once weekly.

Treatment should be continued until any treated nail is clear or its appearance is significantly improved. In some cases, an additional oral therapy may be required.

In general, the treatment duration for fingernails is about 6 months while for toenails it is about 9 to 12 months.

Consult your doctor if:

- the infection has not cleared after the treatment period
- you are not responding adequately to the treatment

- you have a severe nail infection (more than half the nail)
- three or more nails are affected
- the area next to the cuticle, where the nail grows from, is affected.

If you accidentally swallow TERBANE NAIL:

Contact your doctor, pharmacist or nearest hospital if you, or someone else, has swallowed some nail lacquer. Take any remaining medicine and this leaflet with you if possible.

If you missed a dose of TERBANE NAIL:

If you miss an application, apply TERBANE NAIL as soon as possible and then continue your treatment as before. If you only remember at the time of your next application, just apply TERBANE NAIL once and carry on as normal. It is important to try to use TERBANE NAIL at the correct times as forgotten applications may reduce the efficacy of the treatment.

If you stop using TERBANE NAIL:

If you stop treatment with TERBANE NAIL before the recommended period ends, the fungal infection may still remain, and the condition of your nails can get worse again.

4. Possible side effects

TERBANE NAIL can have side effects.

Not all side effects reported for TERBANE NAIL are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using TERBANE NAIL, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop using TERBANE NAIL:

- Skin redness and irritation at the site of application.
- Rash or itching.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of TERBANE NAIL.

Suspected side effects can also be reported directly to the HCR via https://pvi1j.solutions.iqvia.com or the e-mail address, adverse.event.sac@sandoz.com.

5. How to store TERBANE NAIL

- Store at or below 25 °C.
- Keep the bottle tightly closed to avoid drying up of the content.
- Keep the bottle in the carton until required for use.
- TERBANE NAIL must be stored in the original package in order to protect from light.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Discard TERBANE NAIL 6 months after first opening the bottle.
- 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 TERBANE NAIL contains:

The active substance is terbinafine. Each mL of medicated nail lacquer contains terbinafine hydrochloride equivalent to 78,22 mg of terbinafine (10 % *w/w*).

The other ingredients are:

Ethanol 96 %

Hydroxypropyl chitosan (HPCH)

Purified water

What TERBANE NAIL looks like and contents of the pack:

TERBANE NAIL (medicated nail lacquer) is a clear, colourless to yellowish slightly viscous topical solution.

TERBANE NAIL is packed in a clear type III glass bottle with a low-density polyethylene (LDPE) applicator. The applicator incorporates a short LDPE spatula, embedded in an outer polypropylene bottle screw cap. The bottle cap is attached to the applicator, however, is not in contact with the solution.

Pack sizes: 3,3 mL, 6,6 mL

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

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