Tinasil® 1%

Active ingredient(s): terbinafine hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using Tinasil 1%. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Tinasil 1%.

Where to find information in this leaflet:

- 1. Why am I using Tinasil 1%?
- 2. What should I know before I use Tinasil 1%?
- 3. What if I am taking other medicines?
- 4. How do I use Tinasil 1%?
- 5. What should I know while using Tinasil 1%?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Tinasil 1%?

Tinasil 1% contains the active ingredient terbinafine hydrochloride. Tinasil 1% is a topical antifungal.

Tinasil 1% is used to treat tinea of the feet, body and groin region. Tinea, commonly known as ringworm, is an infection of the skin caused by a type of fungi called dermatophytes. Tinea between the toes is commonly known as athlete's foot.

Terbinafine is also useful to treat candida (yeast) infections of the skin. Yeasts are another type of fungus.

2. What should I know before I use Tinasil 1%?

Warnings

Do not use Tinasil 1%:

- if you are allergic to terbinafine hydrochloride, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- if you find that the tube seal has been broken or missing.
 The product has tamper-evident packaging to help protect you from product tampering.
- on children under the age of 12 years old.

Check with your doctor or pharmacist if you:

- have any other medical conditions
- take any medicines for any other conditions.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Do not use this product if you are pregnant or may become pregnant or if you are breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Tinasil 1%.

4. How do I use Tinasil 1%?

How much to use

Apply Tinasil 1% once daily.

- Clean and thoroughly dry the affected areas on your skin.
- Apply a sufficient amount of the cream on the affected skin and surrounding area. Use only a thin layer of cream and rub in gently.
- If you need to apply Tinasil 1% between your toes, fingers or buttocks, under a breast or armpit, or in the groin region, cover the area with gauze after the cream has been applied. This is particularly useful at bedtime. How long you need to apply Tinasil 1% for depends on the type of infection you have:
 - o Tinea (athlete's foot, ringworm, jock itch) 7 days
 - Tinea infection on the sole of the foot 2-4 weeks
 - o Candida (yeast) infections 1-2 weeks

You should apply Tinasil 1% only to the skin outside of the body. Wash your hands after use.

Avoid applying the cream near your eyes or touching your eyes while you still have the cream on your hands. In case of accidental contact with the eyes rinse the eyes thoroughly with running water and if any symptoms persist see your doctor.

Follow the instructions provided with the medicine.

Do not exceed the recommended dosage.

If you accidently take Tinasil 1%

If Tinasil 1% has been accidently swallowed, particularly by a child, contact your doctor or phone the Poisons Information Centre (by calling 13 11 26).

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Tinasil 1%?

Things you should do

While the signs of the infection may disappear after only using Tinasil 1% for a few days, it is important to continue use for the recommended period. The reason is that, if you use it for only a few days, you may not remove all of the fungi from the affected areas, and as a result, the infection may return soon after you stop using the product. If there is no improvement in your condition after using Tinasil 1% for the recommended time, see your doctor or pharmacist.

Looking after your medicine

Store below 25°C

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine (as relevant)

• Do not use after the expiry date shown on the pack.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Less serious/common side effects

Less serious side effects	What to do
RednessItchinessStinging sensation	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What Tinasil 1% contains

Active ingredient	Terbinafine hydrochloride	
(main ingredient)		
Other ingredients sorbitan monostearate		

(inactive ingredients)	cetyl palmitate polysorbate 60 cetyl alcohol stearyl alcohol isopropyl myristate sodium hydroxide
Potential allergens	benzyl alcohol

What Tinasil 1% looks like

Tinasil 1% is a white to almost white cream (AUST R 272452).

Sponsor

Southern Cross Pharma Pty Ltd Suite 2, Level 2, 19-23 Prospect Street Box Hill VIC 3128

Who distributes Tinasil 1%

Alphapharm Pty Ltd trading as Viatris Level 1, 30 The Bond 30-34 Hickson Road Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

TINASIL® is a Viatris company trade mark

This leaflet was prepared in August 2023.

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