

FREEDERM GEL

Terbinafine hydrochloride (1%w/v)

What is in the leaflet

1. What Freederm Gel is used for
2. How Freederm Gel works
3. Before you use Freederm Gel
4. How to use Freederm Gel
5. While you are using it
6. Side Effects
7. Storage and Disposal of Freederm Gel
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Freederm Gel is used for

Freederm Gel contains the active ingredient Terbinafine Hydrochloride which is an antifungal used for the treatment of fungal infection of:

- The groin area.
- The skin (ring worm).
- Toe and finger nails (yellow, opaque and thickened nails).
- The feet (athlete's foot).

How Freederm Gel works

Freederm Gel has a broad-spectrum antifungal activity. Terbinafine works by attacking the fungal growth, eventually causing weakness and death of the fungus.

Before you use Freederm Gel

- When you must not use it

Do not use Freederm Gel if you are hypersensitivity to Terbinafine HCl or any other ingredients in this product (listed under product description).

- Before you start to use it

Pregnancy and lactation –

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

- Taking other medicines

Terbinafine does not generally affect the activity of other medications.

How to use Freederm Gel

- How much to use

Cleanse and dry the infected area thoroughly with warm water before

application. Apply a thin layer onto the infected area and its surroundings. Rub in gently. Treatment can be repeated if necessary.

Wash hand after use to avoid spreading the infection on yourself or to others.

- When to use it

Apply the gel once daily.

- How long to use it

To prevent recurrence, continue to treat the area for one to two weeks after signs or symptoms of infections have gone.

- If you forget to use it

If you forget to use Freederm Gel, use it as soon as you remember then continue your treatment as before. If you only remember at the time of your next application, just apply the cream and carry on as normal.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have use too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Freederm Gel

- Things you must do

Check with your doctor or pharmacist if symptoms persist or gets worse.

- Things you must not do

Do not use Freederm Gel to treat any other conditions unless your doctor or pharmacist told you so.

- Things to be careful of

For external use only. Avoid contact with eyes, nose and mouth. Not to be taken.

Side Effects

Occasionally itching or redness may occur.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Freederm Gel

- Storage

- Store below 30°C.
- Protect from light.
- Keep out of reach of children.

- Disposal

Do not use this medicine after the expiry date or if the tube is leaking or if the tube nozzle cover is broken.

Product Description

- What it looks like

Freederm Gel is a white to off-white smooth gel.

- Ingredients

Active ingredient

Terbinafine HCl 1%w/v

Inactive ingredients

Propylene glycol, carbomer 940, sodium hydroxide 1M, isopropyl myristate, hydrogenated polyisobutene, polysorbate 80, isopropyl alcohol, n-methyl-2pyrrolidone, benzyl alcohol, butylated hydroxytoluene, menthol, purified water.

- MAL Number:

MAL08021538X

Manufacturer and Product Registration Holder

Winwa Medical Sdn Bhd
1952, Lorong I.K.S. Bukit Minyak 3,
Taman I.K.S. Bukit Minyak,
14000 Bukit Mertajam,
Pulau Pinang, Malaysia.

Date of revision

23/02/2021

Serial Number:

NPRA(R4/1)010221/00004

X.EFG-PIL.01