

PACKAGE LEAFLET

Package leaflet: Information for the patient

Nailderm 250 mg Tablets terbinafine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Nailderm is and what it is used for

Nailderm contains a medicine called terbinafine as terbinafine hydrochloride, which belongs to a group of medicines called antifungals. It is used in adults and older people to treat a number of fungal infections of the skin and nails such as athlete's foot, groin infections, ringworm and also onychomycosis (a fungal infection of the nails). It kills the fungus and stops it growing.

2. What you need to know before you take Nailderm

Do not take Nailderm:

- if you are allergic to terbinafine or any of the other ingredients of this medicine (listed in section 6).
- if you have severe kidney problems.
- if you have or had liver problems.
- if you are breastfeeding.
- if you are pregnant or trying to become pregnant.

Do not take Nailderm if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Nailderm.

Warnings and precautions

Talk to your doctor or pharmacist before taking Nailderm:

- if you have or have experienced patches of red/silver skin (psoriasis), or facial rash, joint pain, muscle disorder, fever (cutaneous and systemic lupus erythematosus). Nailderm can make these problems worse.
- if you have ever had a liver or kidney problems.
- if any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Nailderm.

Look out for side effects

Nailderm can cause some side effects that may require urgent medical treatment. They include problems with your liver, skin, muscles or blood. See "Stop taking Nailderm and see a doctor or go to

a hospital straight away, if you notice any of the following serious side effects” at the beginning of Section 4 for more information.

Children and adolescents

Nailderm tablets can be used in adolescents and children aged 2 years and over. As the patient grows, the doctor will adjust the dose.

Nailderm tablets are not recommended for use in children under 2 years of age since there is no experience in this age group.

Other medicines and Nailderm

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription oral contraceptives or herbal medicines. This is because Nailderm can affect the way some other medicines work. Also some other medicines can affect the way Nailderm works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- rifampicin, used to treat infections
- cimetidine, a medicine used to treat stomach problems such as indigestion or stomach ulcers
- anti-fungals, used to treat fungal infections such as fluconazole or ketoconazole
- anti-depressants, including tricyclic anti-depressants such as desipramine SSRIs (selective serotonin reuptake inhibitors), or MAOIs (monoamine oxidase inhibitors)
- oral contraceptives (as irregular periods and breakthrough bleeding may occur in some females)
- caffeine, used in some painkillers or cold remedies
- beta-blockers or anti-arrhythmics, used to treat heart problems such as metoprolol, propafenone or amiodarone
- ciclosporin, used to control your body’s immune system after a transplant
- dextromethorphan, used in some cough medicines

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Nailderm.

Food and drink

Nailderm may increase the effects of caffeine in your drinks.

Pregnancy and breast-feeding

Do not take Nailderm if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

You should not take this medicine if you are breast-feeding as terbinafine can pass into breast milk. Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Nailderm can cause dizziness. If you feel dizzy after taking this medicine, do not drive or use any tools or machines.

Nailderm contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Nailderm

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much to take:

Adults (including the elderly)

Your doctor will decide what dose of Nailderm you should take. The dose will be on the pharmacist's label. Check the label carefully. It should tell you how many tablets to take and how often.

The recommended dose for adults and older people is 250 mg once a day. If your liver or kidneys are not working very well, your doctor may reduce the dose.

The length of your treatment with Nailderm will depend on the type of infection you have, how severe it is and what part of your body is affected.

- For skin infections continue taking the tablets for 2 to 6 weeks.
- For nail infections treatment usually lasts between 6 weeks and 3 months.
- Some patients with toenail infections may need to be treated for 6 months or longer.

How to take

- You should take Nailderm by mouth.
- Swallow the tablets whole with a glass of water.
- Nailderm can be taken with or without food.
- The score line is not intended for breaking the tablet.

Patients with reduced kidney or liver function

Nailderm is not recommended in patients with reduced kidney or liver function.

Use in children and adolescents

There is no experience with Nailderm in children under 2 years of age (usually less than 12 kg).

The dosage in children above 2 years of age depends on the body weight:

Children weighing more than 40 kg 250 mg (one 250 mg tablet) once daily

Other terbinafine products should be used for children weighing 20 to 40 kg (dose of 125 mg) as the tablets cannot be broken into two equal halves.

Other form(s) of this medicine may be more suitable for children; ask your doctor or pharmacist.

Other ways to clear up your infection

There are other steps that you can take to help clear up your infection and make sure that it does not return. For example, keep the infected area dry and cool and change clothing that is in direct contact with the infected area daily.

If you take more Nailderm than you should

If you take too much Nailderm tell your doctor or go to the hospital straight away. Take your medicine pack with you so that people can see what you have taken. You may get a headache, feel sick or dizzy or stomach pain.

If you forget to take Nailderm

If you miss taking a Nailderm tablet, do not worry. Take it as soon as you remember, unless it is less than 4 hours before your next dose is due. In this case, wait and take your next tablet at the usual time. Then carry on as normal until you have finished all the tablets. Do not take a double dose to make up for a forgotten dose.

If you stop taking Nailderm

It is important that you finish all the tablets you have been given unless your doctor tells you to stop taking them.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Nailderm and see a doctor or go to the hospital straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- severe allergic reaction – the signs may include difficulty breathing, swelling of your lips, face, throat or tongue, flushing, stomach cramps or joint pain, stiffness, rash or swollen lymph glands. You may also become unconscious
- yellowing of your skin or eyes. Unusually dark urine or pale faeces, unexplained feeling of sickness, being sick, stomach problems, loss of appetite or unusual tiredness or weakness – these may be signs of liver problems
- a sore throat with fever and shivering – signs that the medicine has affected your blood cell
- a sore throat, with fever, tiredness and ulcers appearing on your mouth or lips – signs of a problem with your immune system
- unusual bleeding or bruising – signs that the medicine has affected your blood cells
- stomach pain which spreads to your back – signs of “pancreatitis”
- unexplained muscle weakness and pain or having dark red-brown urine – signs of “muscle necrosis”
- feeling unusually tired, weak or breathless and looking pale – signs of “anaemia”
- onset or worsening of a condition called psoriasis (a long-term illness with symptoms including thickened patches of red and silver skin)
- severe skin rash (including light sensitivity, swelling, blistering, scales or wheals)
- skin rash, fever, itching, feeling tired or if you notice purplish-reddish spots under your skin – signs that your blood vessels have become inflamed

If you get any of the serious side effects listed above, stop taking Nailderm and see a doctor or go to hospital straight away.

Other side effects include:

Very common: may affect more than 1 in 10 people

- headache
- diarrhoea
- skin rashes (itchy)
- joint pain and muscle pain
- stomach problems such as loss of appetite, stomach ache, indigestion, feeling bloated or sick

Common: may affect up to 1 in 10 people

- feeling tired or dizzy
- depression
- disturbance or loss of sense of taste
- eye disorder

Uncommon: may affect up to 1 in 100 people

- if you notice unusually pale skin, nail beds or when you pull down your eyelids, feeling unusually tired, weak or breathless during physical activity (possible signs of a disease that affects the level of red blood cells), anxiety, tingling or numbness and decreased skin sensitivity, increased sensitivity of the skin to sun, noises (e.g. hissing) in ears, fever and weight loss.

Rare: affecting fewer than 1 in 1,000 people

- yellow eyes or skin (liver problems) and abnormal liver function test results

Very rare: may affect up to 1 in 10,000 people

- numbness, tingling or loss of sensitivity to touch

- hair loss

Not known: frequency cannot be estimated from the available data

- loss or sense of smell or reduced ability to smell
- blurred vision, decreased sharpness of vision
- feeling anxious – signs include trouble sleeping, feeling tired, lack of energy, finding it difficult to think or concentrate
- feeling low in mood
- increase in blood level of a muscle enzyme – shown in blood tests
- skin rash due to high level of a specific type of white blood cells

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nailderm

Keep this medicine out of the sight and reach of children.

Do not take this medicine after the expiry date stated on the label or carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Nailderm contains

- The active substance is terbinafine hydrochloride equivalent to 250 mg of terbinafine.
- The other ingredients are colloidal anhydrous silica, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, povidone and talc.

What Nailderm looks like and the contents of the pack

Nailderm is a white to off-white round tablet marked 'TF/250' on one side and 'G' on the other. Nailderm is available in plastic bottles or blister packs of 7, 8, 14, 28, 30, 42, 56, 98, 100 or 250 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35-36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Manufacturers

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35-36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Mylan Hungary Kft., Mylan utca 1., Komárom, 2900, Hungary.

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland	Nalderm 250 mg Tablets
Portugal	Terbinafina Mylan 250 mg Comprimidos
United Kingdom	Terbinafine 250 mg Tablets

This leaflet was last revised in 07/2022.