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

Nailderm contains the active substance terbinafine as terbinafine hydrochloride, which belongs to a group of medicines called antifungals. It is used to treat a variety of fungal infections of the skin such as athlete's foot, groin infections, ringworm and also onychomycosis (a fungal infection of the nails).

2. What you need to know before you take Nailderm

Do not take Nailderm:
- if you are allergic to terbinafine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you have severe kidney problems.
- if you have liver problems.

Warnings and precautions

Talk to your doctor before taking Nailderm:
- if you have psoriasis, a skin condition causing red scaly patches (see section 4).
- if you have a condition called systemic lupus erythematosus (SLE)
- if you have a kidney problem, taking terbinafine is not recommended.

If during treatment with Nailderm one of the following symptoms occur:
- symptoms that may indicate a liver problem such as persistent itching, nausea, stomach pain, loss of appetite (anorexia), tiredness, vomiting, jaundice, dark urine or pale stools
- symptoms that may indicate a blood disorder, for example, you bleed or bruise more easily than normal or you are prone to infections
- high fever or sore throat, severe itching, severe skin diseases or skin diseases where mucosa is affected
- allergic condition which causes joint pain, skin rashes and fever

Stop using Nailderm and consult your doctor (see section 4)

Your doctor may perform a blood test before beginning treatment.

Other medicines and Nailderm
Tell your doctor if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription, herbal medicines or any of the following:

- rifampicin, an antibiotic used to treat infections
- cimetidine a medicine for stomach ulcers or heartburn
- medicines used to treat fungal infections such as fluconazole, ketoconazole
- medicines used to treat irregular heart rhythm e.g. amiodarone, flecainide
- antidepressant medicine such as amitriptyline, desipramine, fluoxetine, fluvoxamine, phenelzine, tranylcypromine
- oral contraceptives, when taken at the same time may cause menstrual bleeding and irregular periods
- caffeine
- medicines for high blood pressure called beta-blockers such as atenolol, propranolol, labetalol.
- ciclosporin, a medicine used to control your body's immune system in order to prevent rejection of transplanted organs
- warfarin, a medicine used to thin your blood
- medicines used to treat cough such as dextromethorphan

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
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
If you feel dizzy or giddy, you should avoid driving vehicles or using 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.

The recommended dose is:

Adults (including the elderly)
One 250 mg tablet once a day. For skin infections treatment usually lasts for two to six weeks. For nail infections treatment usually lasts for six to twelve weeks, although some patients with toenail infections may need to be treated for six months.

It is important that you complete the course of treatment as directed by your doctor, even if your condition improves.

How to take

- Swallow the tablets with a glass of water. The tablet should be taken at the same time each day, before or after a meal**.**
- 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
Nailderm is not recommended for children and adolescents under 18 years.

If you take more Nailderm than you should
Contact your doctor or nearest hospital emergency department **immediately**. Take the container and any remaining tablets with you. Symptoms of overdose include headache, feeling sick, stomach pain and dizziness.

If you forget to take Nailderm
Take your dose as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop using Nailderm
Do not stop taking Nailderm without talking to your doctor first. It is important to finish the course of treatment as directed by your doctor.

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.

If you notice any of the following side effects, stop taking the tablets and tell your doctor immediately or go to your nearest hospital emergency department:

Rare: may affect up to 1 in 1,000 people
- liver problems, which may cause dark urine or pale stools, yellowing of the skin or whites of the eyes, itching of the skin, feeling generally unwell
- hypersensitivity reaction which can cause fever, swelling, skin rash, swollen glands in the neck or under the armpits

Very rare: may affect up to 1 in 10,000 people
- severe skin reactions including itching, sensitivity to light, blistering of the skin, mouth, eyes and genitals, flaking or peeling of the skin
- onset or worsening of SLE (lupus), an allergic reaction causing joint pain, skin rashes and fever
- an increase in the number of infections and fevers that you get (e.g. sore throat, mouth ulcers). This may be caused by changes in the number or type of white blood cells
- allergic reactions such as skin rashes, red itchy swollen skin, swelling of the face or throat, tightness of the chest and difficulty breathing
- an increase in the number of infections and fevers that you may get (e.g. sore throat, mouth ulcers), feeling tired or lacking energy, or if you notice that you bruise or bleed (e.g. nose bleeds) more easily or without explanation. These may be signs of more serious changes in the number, or type, of certain blood cells

Not known: frequency cannot be estimated from the available data
- abnormal muscle breakdown (weakness or pain) which can lead to kidney problems
- inflammation of the pancreas which causes severe pain in the abdomen and back
- flu-like symptoms with a rash on the face, high temperature, swollen glands (lumps on the neck or under the arm pits), increased levels of liver enzymes and an increase in a type of white blood cell (eosinophilia), which can be seen in blood tests. These may be signs of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)

Other side effects may include:

Very common: may affect more than 1 in 10 people
- reduced appetite
- feeling of fullness
- bloating of the stomach
- stomach pain
- diarrhoea
- indigestion
- feeling sick (nausea)
- skin rash or nettle-like rash (hives). If your skin rash gets worse stop taking this medicine and contact your doctor
- joint or muscle pain

Common: may affect up to 1 in 10 people
- headache
- tiredness

Uncommon: may affect up to 1 in 100 people
- loss or change of taste, usually reversible on stopping treatment.
- weight loss as a result of taste disturbances

Rare: affecting fewer than 1 in 1,000 people
- dizziness
- loss or reduction of sense of touch
- tingling, pins and needles
- increases in liver enzymes (may be found on a blood test result)
- feeling generally unwell

Very rare: may affect up to 1 in 10,000 people
- anxiety
- feeling depressed
- sensitivity of the skin to light
- psoriasis like skin eruptions or worsening of psoriasis (skin rash with thickened patches of red skin, often with silvery scales)
- hair loss
- break-through bleeding during the menstrual cycle in some women and irregular cycles
- spinning sensation, which may be accompanied by dizziness

Not known: frequency cannot be estimated from the available data
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- change in ability to smell, loss of smell, which may be permanent
- problems with your eyesight, reduced or blurred vision
- loss or reduction in hearing
- ringing in the ears
- inflammation of blood vessels, often with skin rash
- flu-like illness, fever
- increase in blood levels of a muscle enzyme called creatine phosphokinase (may be found on a blood test)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. 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.

Generics [UK] Limited, Station Close, Potters Bar, Hertfordshire EN6 1TL, United Kingdom.

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

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

This leaflet was last revised in 08/2020