

Package leaflet: Information for the patient

Nortriptyline 10 mg film-coated Tablets
Nortriptyline 25 mg film-coated Tablets
Nortriptyline 50 mg film-coated Tablets
 Nortriptyline hydrochloride

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, pharmacist or nurse.
- 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 or if you notice any side effects not listed in this leaflet talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Nortriptyline tablets are and what they are used for
2. What you need to know before you take Nortriptyline tablets
3. How to take Nortriptyline tablets
4. Possible side-effects
5. How to store Nortriptyline tablets
6. Contents of the pack and other information

1. What Nortriptyline tablets are and what they are used for

Nortriptyline tablets contain the active ingredient nortriptyline hydrochloride, which is a tricyclic antidepressant. Nortriptyline tablets relieves symptoms of depression.

Nortriptyline tablets may also be used for the treatment of bed-wetting in children 6 years and older.

2. What you need to know before you take Nortriptyline tablets

Do not take Nortriptyline tablets:

- If you are **allergic (hypersensitive)** to nortriptyline hydrochloride or any of the other ingredients of Nortriptyline tablets (see list of ingredients in Section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue;
- If you have had a **recent heart attack or heartbeat disorder**;
- If you have **severe liver disease**;
- If you suffer from **mania** (abnormally raised mood);
- If you are **breast-feeding**;
- If the **child is under 6 years of age**;
- If you are taking, or have taken in the last two weeks, **monoamine oxidase inhibitors** (another type of antidepressant);
- If you are taking **adrenaline-like drugs** including ephedrine, isoprenaline, noradrenaline, phenylephrine and phenylpropanolamine. These drugs are often contained in cough and cold remedies.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Nortriptyline tablets

- If you feel **suicidal** or **aggressive** - tell your doctor;
- If you are **agitated, overactive** or suffer from **schizophrenia**;
- If you have **heart disease**;
- If you have a **thyroid condition**;
- If you have a **history of epilepsy**;
- If you have high pressure in the eyes (**glaucoma**);
- If you have an **enlarged prostate**;
- If **your child taking Nortriptyline tablets has a change in behaviour**;
- If you are going to have **electroconvulsive therapy** (electric shock);
- If you are **diabetic**;
- If you are going to receive an **anaesthetic**, e.g. for an operation – tell your doctor;
- If you have had **an allergic reaction to another tricyclic antidepressant** in the past;
- If you are pregnant, think you might be pregnant or planning to become pregnant or breast-feeding you should not take Nortriptyline tablets unless your doctor tells you to.

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself;
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to hospital straight away.**

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

If any of the above applies to you, tell your doctor or pharmacist.

Other medicines and Nortriptyline

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The following medicines may interact with your Nortriptyline tablets:

- **guanethidine, debrisoquine, bethanidine, clonidine** (used to treat high blood pressure);
- **barbiturates** (used for anxiety or to make you feel sleepy);
- **alcohol** (you should not drink alcohol);
- **fluoxetine** (another antidepressant);
- **cimetidine** (for heartburn and ulcers);
- **phenothiazines** (for mental illness);
- **carbamazepine** (for epilepsy);
- **propafenone, flecainide, encainide, quinidine** (for heartbeat disorders);
- **valproic acid** (medicine used for the treatment of epilepsy and bipolar disorder).

It may still be all right for you to be given Nortriptyline tablets. Your doctor will be able to decide what is suitable for you.

Pregnancy and breast-feeding

The safety of nortriptyline for use during pregnancy has not been established.

Do not take Nortriptyline tablets if you are breast-feeding.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Nortriptyline tablets may affect alertness. Use caution when driving or operating heavy machinery until you're aware of how this drug affects you. If you feel Nortriptyline tablets affect your ability to drive or use machines, tell your doctor immediately.

Nortriptyline tablets contain lactose

Nortriptyline tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Nortriptyline tablets

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

Dosage

Adults:

The recommended adult dose is 25mg three or four times daily or the dose may be given once a day, usually at night.

The dose should begin at a low level, 10mg, 3-4 times daily, for example and be increased gradually as required. The maximum dose is 150mg per day.

The elderly:

The recommended dose is 30 to 50mg/day in divided doses.

Treatment may start with 10mg three times a day. 50 mg tablets are not appropriate for use in elderly patients.

Adolescent patients:

The recommended dose is 30 to 50mg/day in divided doses.

Treatment may start with 10mg three times a day. 50 mg tablets are not appropriate for use in adolescent patients.

Lower dosages are recommended for outpatients than for patients in hospital who will be under close supervision.

Following remission maintenance treatment may be needed longer term.

This should be at the lowest dose that stops the symptoms of depression coming back.

Use in Children and adolescents (for bed-wetting only)

Age (years)	Weight		Dose (mg)
	Kg	lb	
6-7	20-25	44-55	10
8-11	25-35	55-77	10-20
Over 11	35-54	77-119	25-35

The dose should be given thirty minutes before bedtime.

The maximum length of treatment should be three months. Another course of treatment should not be started until a full physical examination has been made. 50 mg tablets are not appropriate for use in children and adolescents.

If you take more Nortriptyline tablets than you should

Go to the nearest casualty department or contact your doctor immediately. Take the tablet carton with you.

If you forget to take Nortriptyline tablets

If you miss a dose, take one as soon as you can. If you have missed several doses, tell your doctor. Do not take a double dose to make up for a forgotten dose.

If you stop taking Nortriptyline tablets

Do not stop taking the tablets or reduce the dose without telling your doctor first. If you suddenly stop taking the tablets you may feel sick (nausea), have a headache or feel generally unwell. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side-effects

Like all medicines, Nortriptyline tablets can cause side effects, although not everybody gets them. **If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

All medicines can cause allergic reactions, although serious allergic reactions are very rare.

Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching, especially affecting your whole body.

The following side effects have been reported (Not known: frequency cannot be estimated from the available data):

- low or high blood pressure
- fast or irregular heartbeat
- palpitations
- heart attack (myocardial infarction)
- stroke
- oedema (swelling of the ankles)
- confusion (especially in the elderly) with seeing or hearing things (hallucinations)
- not knowing where you are (disorientation)
- false beliefs (delusions)
- anxiety, restlessness, agitation
- not sleeping (insomnia)
- nightmares
- panic
- long-lasting abnormal mood
- worsening of mental illness
- numbness, tingling, pins and needles in the hands or feet
- coordination problems
- tremors
- abnormal movements
- fits (seizures)
- altered brainwave (EEG) patterns
- ringing in the ears (tinnitus)
- dry mouth
- rarely, inflamed glands under the tongue or inflammation of the gums (gingivitis)
- blurred vision, difficulty in focusing, dilated pupils
- constipation, blockage of the digestive tract
- unable to urinate or delayed urination
- rash
- itching
- light sensitivity
- swelling (oedema)
- fever
- reaction to other similar drugs
- blood disorders which may cause you to bruise easily, become anaemic or be unable to fight off infections
- feeling sick (nausea) and vomiting
- not eating (anorexia)
- indigestion
- diarrhoea
- constipation.
- peculiar taste
- inflamed mouth
- abdominal cramps
- black tongue
- development of breasts in men, breast enlargement and milk production in women
- increased or decreased sex drive
- failure to have an erection (impotence)
- swollen testicles
- altered blood sugar levels
- yellow eyes and skin (jaundice)
- altered liver function
- inflamed liver (hepatitis) and liver damage
- weight gain or loss
- sweating
- flushing
- urinating often and at night
- sleepiness
- dizziness
- weakness
- tiredness
- headache
- swollen glands
- hair loss (alopecia).
- An increased risk of bone fractures has been observed in patients taking this type of medicine.

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 (see details). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Nortriptyline tablets

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

Do not use this medicine after the expiry date which is stated on the blister, label or carton after EXP. The expiry date refers to the last day of that month.

HDPE containers:

This medicinal product does not require any special storage conditions.

After first opening use within 5 months.

Blisters:

This medicinal product does not require any special storage conditions.

Storing your medicine

Do not use this medicine if you notice any signs of deterioration (for instance change in color)

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 Nortriptyline tablets contain

- The active ingredient is nortriptyline hydrochloride.
Each film-coated tablet contains nortriptyline hydrochloride equivalent to 10 mg, 25 mg, 50 mg nortriptyline base.
- The other ingredients are lactose monohydrate, maize starch, calcium hydrogen phosphate anhydrous, magnesium stearate.
- *Coating:*
- Opadry II Clear:
- Polyvinyl alcohol E 1203
- Polyethyleneglycol / macrogol
- Talc.

What Nortriptyline tablets looks like and contents of the pack

The 10mg tablets are white, round, biconvex film-coated tablets, marked "N10", 5.5 mm in diameter.

The 25mg tablets are white, round, biconvex film-coated tablets, marked "N25", 8.0 mm in diameter.

The 50mg tablets are white, round, biconvex film-coated tablets, marked "N50", 10.2 mm in diameter.

Nortriptyline tablets are available in:

- HDPE bottles with an LDPE, HDPE-lined screw cap with silica gel in pack sizes of 100 tablets.
- PVC/PVDC Blisters lidded with aluminium foil available in pack sizes of 30 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Focus Pharmaceuticals Limited
Capital House,
85 King William Street,
London, EC4N 7BL,
UK

Manufacturer

Anfarm Hellas SA
Sximatari Viotias, 32009, Greece

This leaflet was last revised in March 2019