

**Package leaflet:  
Information for the user  
Nortriptyline 10 mg  
film-coated tablets  
Nortriptyline 25 mg  
film-coated tablets**

**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 Nortriptyline tablets is and what it is 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 relieve the symptoms of depression.

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

**Do not take Nortriptyline tablets if:**

- you are allergic (hypersensitive) to nortriptyline or any of the other ingredients of Nortriptyline tablets (listed in section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue;
- you have had a recent heart attack or heartbeat disorder;
- you have severe liver disease;
- you suffer from mania (abnormally raised mood);
- you are breast-feeding;
- the child is under 6 years of age;
- you are taking, or have taken in the last two weeks, monoamine oxidase inhibitors (another type of antidepressant);
  - 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 taking medicines containing buprenorphine, including buprenorphine/ naloxone used for treatment of opioid addiction. The use of these medicines together with Nortriptyline tablets can lead to serotonin syndrome, a potentially life-threatening condition (see “other medicines and Nortriptyline tablets”)

**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 a 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.

**Other medicines and Nortriptyline tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This may include medicines obtained without a prescription. Some medicines may increase the side effects of Nortriptyline tablets and may sometimes cause very serious reactions. Do not take any other medicines whilst taking nortriptyline tablets without first talking to your doctor, especially:

- medicines containing buprenorphine, including buprenorphine/ naloxone used for treatment of opioid addiction. These medicines may interact with Nortriptyline tablets and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

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** (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.

**Taking Nortriptyline tablets with alcohol**

You should **not** drink alcohol while you are being treated with Nortriptyline tablets as alcohol might increase the sedative effect.

**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 for advice before taking this medicine.

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

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

**Driving and using machines**

Nortriptyline hydrochloride 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 contains lactose monohydrate.** 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 this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

**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.
- If your doctor tells you to take more than four 25mg tablets a day, he or she may arrange for you to have regular blood tests.

**The elderly:**

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

Treatment may start at a low level (10-20 mg daily) and may be increased as required to the maximum dose of 50mg. If you require a dose of 50mg or over, your doctor will arrange for you to have a recording of your heart (ECG) and blood tests.

Half Fold: 275mm

The 50mg tablets are not appropriate for use in elderly patients.

#### Renal impairment

In case of renal impairment, your doctor will increase or decrease the dose carefully and gradually. In most cases, however, the usual dosage will be given.

#### Hepatic impairment

Patients with liver diseases or people known as "poor metabolisers" usually receive lower doses. Your doctor may take blood samples to determine the level of nortriptyline in the blood.

#### Use in children and adolescent patients:

Nortriptyline tablets should not be used in children and adolescents aged less than 18 years, as safety and efficacy have not been established.

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

#### Duration of treatment

It may take a few weeks before you feel any improvement. Following remission maintenance treatment may be needed longer term, usually up to 6 months. This should be at the lowest dose that stops the symptoms of depression coming back.

#### If you take more Nortriptyline tablets than you should

Do not take more tablets than your doctor tells you to. If you ever take too many, or if a child has taken any nortriptyline, go to the nearest hospital casualty department or tell your doctor at once.

#### 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 using 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:

- 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 via the national reporting system listed in Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Nortriptyline

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 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 medicines you no longer use. These measures will help protect the environment.

#### 6. Contents of the pack and other information

##### What Nortriptyline contains

- The active substances is Nortriptyline.  
Each film-coated tablet contains 10 mg nortriptyline (as nortriptyline hydrochloride).  
Each film-coated tablet contains 25 mg nortriptyline (as nortriptyline hydrochloride).
- The other ingredients are:  
*Tablet core:* Lactose Monohydrate, maize Starch, Calcium Hydrogen Phosphate, magnesium Stearate  
*Tablet coating:* Lactose Monohydrate, hypromellose 2910, titanium dioxide, triacetin

##### What Nortriptyline looks like and contents of the pack

Film-coated tablet.

*Nortriptyline 10 mg film-coated tablet*  
White to off-white, round shaped, film coated tablets debossed with 'N' on one side and '10' on other side.

*Nortriptyline 25 mg film-coated tablet*  
White to off-white, round shaped, film coated tablets debossed with 'N' on one side and '25' on other side.

Nortriptyline film-coated tablets are available in blister pack and HDPE packs.

Blister pack: 100 film-coated tablets.  
HDPE bottle pack: 100 film-coated tablets.

Not all pack sizes may be marketed.

##### Marketing Authorisation Holder and Manufacturer

Milpharm Limited  
Ares Block, Odyssey Business Park  
West End Road  
Ruislip HA4 6QD  
United Kingdom

##### Manufacturer

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Or

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