PACKAGE LEAFLET

Package leaflet: Information for the user

Nortriptyline 50 mg film-coated tablets
nortriptyline

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

1. What Nortriptyline is and what it is used for

Nortriptyline contains the active ingredient nortriptyline hydrochloride, which is a tricyclic antidepressant. Nortriptyline is used to treat **major depression in adults.**

2. What you need to know before you take Nortriptyline

Do not take Nortriptyline if:
- you are **allergic** (hypersensitive) to nortriptyline or any of the other ingredients of Nortriptyline (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
- you have had a **recent heart attack** or heartbeat disorder, heart block or coronary artery disease
- you are taking, or have stopped taking within the last 14 days, a monoamine oxidase inhibitor (e.g. **phenelzine, isocarboxazid or tranylcypromine**). If you are taking **moclobemide** you must stop this at least 24 hours before starting nortriptyline
- You have to stop treatment with Nortriptyline and wait for 14 days before you start treatment with a monoamine oxidase inhibitor

Warnings and precautions
Talk to your doctor before taking these tablets if:
- you feel **suicidal** or **aggressive**
- you are **agitated**, **overactive**, or suffer from **schizophrenia**
- you have **heart disease**
- you have a cardiac condition called **Brugada syndrome**
- you have a **thyroid** condition or receive thyroid medication
- you have a history of **epilepsy**
- you have high pressure in the eyes (**glaucoma**)

- you have an enlarged **prostate**
- you are going to have electroconvulsive therapy (**electric shock**)
- you are **diabetic** as you might need and adjustment of your antidiabetic medicine
- you are going to receive an **anaesthetic**, e.g. for an operation - tell your doctor as it might be necessary to stop the treatment with nortriptyline before you are given anaesthetics
- you have had an **allergic reaction** to another tricyclic antidepressant in the past
- you have difficulty in **passing urine**
- you have **bipolar disorder**, as some patients may enter into a manic phase
- you have pylorus stenosis (**narrowing of the gastric outlet**) and paralytic ileus (**blocked intestine**)
- you have excessive fever (hyperpyrexia)
- you are going to have electroconvulsive therapy
- you are elderly as you are more likely to suffer from certain side effects, such as dizziness when you stand up due to low blood pressure (see also section 4 Possible side effects)
- you have severe **liver disease**

Prolonged QT interval
A heart problem called 'prolonged QT interval' (which is shown on your electrocardiogram, ECG) and heart rhythm disorders (rapid or irregular heart beat) have been reported with Nortriptyline. Tell your doctor if you:
- have slow heart rate
- have or had a problem where your heart cannot pump the blood round your body as well as it should (a condition called heart failure)
- are taking any other medication that may cause heart problems, or
- have a problem that gives you a low level of potassium or magnesium, or a high level of potassium in your blood

Thoughts of suicide and worsening of your depression
If you are depressed 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 and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

Children and adolescents
Do not give this medicine to children and adolescents aged below 18 years for these treatments as safety and efficacy have not been established in this age group.

Other medicines and Nortriptyline
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
- monoamine oxidase inhibitors

- (MAOIs) e.g. moclobemide, phenelzine, iproniazid, isocarboxazid, nialamide or tranylcypromine (used to treat depression) or selegiline (used to treat Parkinson's disease). These should not be taken at the same time as Nortriptyline (see section 2 Do not take Nortriptyline)
- buprenorphine. This medicine may interact with Nortriptyline 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.
- adrenaline, ephedrine, isoprenaline, noradrenaline, phenylephrine and phenyl - propanolamine (these may be present in cough or cold medicine, and in some anaesthetics)
- medicine to treat high blood pressure for example calcium channel blockers (e.g. diltiazem and verapamil), guanethidine, debrisoquine, bethanidine, clonidine reserpine and methyldopa
- Anticholinergic drugs such as certain medicines to treat Parkinson's disease and gastrointestinal disorders (e.g. atropine, hyoscyamine)
- thioridazine (used to treat schizophrenia)
- tramadol (painkiller)
- medicines to treat fungal infections (e.g. fluconazole, terbinafine, ketoconazole, and itraconazole)
- sedatives (e.g. barbiturates)
- antidepressants (e.g. SSRIs (fluoxetine, paroxetine, fluvoxamine), and bupropion)
- medicines for certain heart conditions (e.g. beta blockers and antiarrhythmics)
- cimetidine (used to treat stomach ulcers)
- methylphenidate (used to treat ADHD)
- oral contraceptives
- rifampicin (to treat infections)
- phenytoin and carbamazepine (used to treat epilepsy)
- St. John's Wort (*Hypericum perforatum*) a herbal remedy used for depression
- thyroid medication.

You should also tell your doctor if you take or have recently taken medicine that may affect the heart´s rhythm. e.g.:

- medicines to treat irregular heartbeats (e.g. quinidine and sotalol)
- astemizole and terfenadine (used to treat allergies and hay fever)
- medicines used to treat some mental illnesses (e.g. pimozide and sertindole)
- cisapride (used to treat certain types of indigestion)
- halofantrine (used to treat malaria)
- methadone (used to treat pain and for detoxification)
- diuretics ('water tablets' e.g. furosemide)
- valproic acid (medicine used for the treatment of epilepsy and bipolar disorder)

If you are going to have an operation and receive general or local anaesthetics, you should tell your doctor that you are taking this medicine. Likewise, you should tell your dentist that you take this medicine if you are to receive a local anaesthetic.

Taking Nortriptyline with alcohol
You should **not** drink alcohol while you are being treated with Nortriptyline 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.
Nortriptyline should not be used during pregnancy unless your doctor considers it clearly necessary and only after careful consideration of the benefit and risk. If you have taken this medicine during the last part

of the pregnancy, the newborn may have withdrawal symptoms such as irritability, increased muscle tension, tremor, irregular breathing, poor drinking, loud crying, urinary retention, and constipation. Your doctor will advise you whether to start/continue/ stop breast-feeding, or stop using this medicine taking into account the benefit of breastfeeding for your child and the benefit of therapy for you.

Driving and using machines
Do not drive or use machinery when you are on Nortriptyline unless you are sure your judgement and co-ordination are not affected. Antidepressants may affect your ability to drive or to operate machinery safely.

Nortriptyline contains 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

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

Nortriptyline film-coated tablets are also available in lower strengths (10 mg and 25 mg tablets).

Adults
- The recommended adult dose is 25 mg 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, 10 mg, 3-4 times daily, for example and be increased gradually as required. The maximum dose is 150 mg per day.
- If your doctor tells you to take more than four 25 mg tablets a day, he or she may arrange for you to have regular blood tests.

Elderly
The usual dose is 30 to 50 mg/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 50 mg. If you require a dose of 50 mg or over, your doctor will arrange for you to have a recording of your heart (ECG) and blood tests.

The 50 mg 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
Nortriptyline 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 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.
Symptoms of overdose include blurred vision, fast or irregular heartbeats, difficulties passing water, dry mouth and tongue, intestinal blockage, fits, fever, agitation, confusion, hallucinations, uncontrolled movements, low blood pressure, weak pulse, pallor, difficulty breathing, blue discolouration of the skin, decreased heart rate, drowsiness, loss of consciousness, coma, various cardiac symptoms such as heart block, heart failure, cardiogenic shock, metabolic acidosis, hypokalaemia.
An overdose can be very dangerous.

If you forget to take Nortriptyline
If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose do not take a double dose to make up for a forgotten dose, just carry on as before. If you have missed several doses, discuss this with your doctor.

If you stop using Nortriptyline
Antidepressants may not make you feel better for the first two weeks or more of treatment, so keep taking Nortriptyline until your doctor tells you to stop. Do not stop these tablets without discussing it with your doctor first.
If you stop using Nortriptyline abruptly after prolong therapy you may have withdrawal symptoms, including not being able to sleep, headache, nausea, irritability and sweating.

4. Possible side effects

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

Tell your doctor immediately if you experience any of the following:

Rare (may affect up to 1 in 1,000 people):
- bad constipation, a swollen stomach, fever and vomiting. These symptoms may be due to parts of the intestine becoming paralysed
- any yellowing of the skin and the white in the eyes (jaundice). Your liver may be affected
- bruising, bleeding, pallor or persistent sore throat and fever. These symptoms can be the first signs that your blood or bone marrow may be affected. Effects on the blood could be a decrease in the number of red cells (which carry oxygen around the body), white cells (which help to fight infection) and platelets (which help with clotting)
- suicidal thoughts or behaviour

Very rare (may affect up to 1 in 10,000 people):
- attacks of intermittent blurring of vision, rainbow vision, and eye pain. You should immediately have an eye examination before the treatment with this medicine can be continued. This condition may be signs of acute glaucoma

Not known (frequency cannot be estimated from the available):
- 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. (signs of serotonin syndrome, a potentially life-threatening condition).
- Brugada Syndrome (unmasking) (symptoms may include very fast heartbeat, dizziness, fainting, seizures). Tell your doctor straight away if you get these symptoms.

The following side effects have also been reported:

Very common (may affect more than 1 in 10 people):
- dry mouth
- excessive sweating
- constipation
- nausea (feeling sick)
- headache
- tremor
- dizziness
- blocked nose
- accommodation disorder of the eyes
- irregular or heavy heart beats
- weight gain
- aggression

Common (may affect up to 1 in 10 people):
- strange body movements
- flushing
- weakness
- fatigue
- dizziness when you stand up due to low blood pressure (orthostatic hypotension)
- disturbed coordination
- disturbed attention
- confusion
- heart block
- a heart problem called 'prolonged QT interval' (which is shown on your electrocardiogram, ECG)
- changes in taste
- blurred vision (dilated pupils)
- decreases in libido and erectile dysfunction
- agitation
- tingling in arms & legs
- problems urinating (increased or decreased)
- feeling thirsty
- low sodium concentration in the blood

Uncommon (may affect up to 1 in 100 people):
- changes in sleep patterns (including nightmares)
- numbness
- vomiting
- high blood pressure
- anxiety
- loss of appetite
- diarrhoea
- liver problems including jaundice

- changes in sexual performance
- increased production or outflow of breast milk without breast feeding
- increased pressure in the eye ball
- collapse conditions
- worsening of cardiac failure
- convulsions (body muscles contract and relax rapidly and repeatedly, resulting in an uncontrolled shaking of the body)
- ringing sounds in ear
- an enlarged or swollen tongue
- skin rash
- swelling of the face

Rare (may affect up to 1 in 1,000 people):
- mouth or gum problems
- confusional states **(delirium)**, especially in the elderly perhaps with anxiety and restlessness
- hallucinations (in patients with schizophrenia)
- more serious heart problems along with ringing in the ears, stomach cramps and clumsiness can also occasionally occur
- increases in libido have been reported.
- a rash, which may be itchy or get worse in sunlight.
- Withdrawal symptoms; if you suddenly stop taking the tablets, you may not be able to sleep and may feel irritable or sweaty
- Decreased appetite
- Hair loss
- Enlargement of male breast tissue
- Weight loss
- abnormal results of liver function tests
- fever

Very rare (may affect up to 1 in 10,000 people):
- alterations in brain function (including perhaps seizures)
- swelling of ankles and in severe cases of the face & tongue
- blood disorders may also occur along with changes in blood sugar level. In severe cases men may suffer from swelling of breasts & testicles whilst women may also notice an increase in breast size and spontaneous lactation. In extreme cases there may be swelling & damage to liver cells.
- Increased pressure within eye
- abnormal heart rhythm that can lead to sudden cardiac death (so called torsades de pointes)
- heart muscle disease
- feeling of inner restlessness and a compelling need to be in constant motion
- disorder of the peripheral nerves
- allergic inflammation of the lung alveoli and of the lung tissue

Not known (frequency cannot be estimated from the available):
- changes of blood sugar levels
- paranoia
- movement disorders (involuntary movements or decreased movements)
- hypersensitivity inflammation of heart muscle
- hepatitis
- syndrome of inappropriate secretion of antidiuretic hormone (SIADH)
- low sodium concentration in the blood

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 Yellow Card Scheme at:www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App. 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 blister, carton or bottle 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 substance is nortriptyline.
Each 50 mg film-coated tablet contains 57 mg of nortriptyline (as hydrochloride).

The other ingredients are:
Tablet core: lactose monohydrate (see section 2 'Nortriptyline contains lactose'), maize starch, microcrystalline cellulose (E460), magnesium stearate (E470b)
Tablet film-coating: hypromellose (E464), titanium dioxide (E171), macrogol

What Nortriptyline looks like and contents of the pack
Nortriptyline 50 mg film-coated tablets are white, round, 9.8 mm in diameter and debossed with '50' on one side.

Nortriptyline 50 mg film-coated tablets are available in blisters packs containing 30 or 100 tablets and in plastic bottles containing 100 or 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Mylan,
Station Close,
Potters Bar,
Herts EN6 1TL
United Kingdom

Manufacturers
Mylan Hungary Kft., H-2900 Komárom, Mylan utca. 1, Hungary

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Other sources of information

This leaflet is also available in other formats for partially-sighted patients. To request a copy of this leaflet in large print please call the Medical Information Direct Line:

+44 (0)1707 853 000 (UK only)