Changed Size
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Package leaflet: Information for the user

Nortriptyline 10mg and 25mg 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 tablets are 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 it is used for

Nortriptyline tablets contains the active substance Nortriptyline which is a tricyclic antidepressant.

Nortriptyline tablets used to treat depression (major depressive episodes) in adults

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

Do not take this medicine:

- If you are allergic to the nortriptyline or any of the other ingredients of this medicine listed in section 6).
- if you recently have had a heart attack (myocardial infarction)
- if you have heart problems such as disturbances in heart rhythm which are seen on an electrocardiogram (ECG), heart block, or coronary artery disease
- if you are taking medicines known as monoamine oxidase inhibitors (MAOIs)
- if you have taken MAOIs within the last 14 days
- if you have taken moclobemide the day before
- if you have severe liver disease

If you are treated with nortriptyline tablets, you have to stop taking this medicine and wait for 14 days before you start treatment with a MAOI.

Warnings and precautions

Talk to your doctor or pharmacist before taking nortriptyline tablets

Heart rhythm disorders and hypotension may occur if you receive a high dosage of nortriptyline. This might also occur in usual doses if you have pre-existing heart disease.

Depression or other conditions that are treated with antidepressants. 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").

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
- have a surgery planned as it might be necessary to stop the treatment with nortriptyline before you are given anaesthetics. In the case of acute surgery, the anaesthetist should be informed about the treatment of amitriptyline.
- have an over active thyroid gland or receive thyroid medication.

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 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.

Episodes of mania

Some patients with manic-depressive illness may enter into a manic phase. This is characterized by profuse and rapidly changing ideas, exaggerated gaiety and excessive physical activity. In such cases, it is important to contact your doctor who probably will change your medication.

Tell your doctor if you have, or have had in the past, any medical problems, especially if you have

- narrow angle glaucoma (loss of vision due to abnormally high pressure in the eye)
- epilepsy, a history of convulsions or fits
- difficulty in passing urine
- enlarged prostate
- thyroid disease
- bipolar disorder
- schizophrenia
- pylorus stenosis (narrowing of the gastric outlet) and paralytic ileus (blocked intestine)
- diabetes as you might need and adjustment of your antidiabetic medicine.

If you use antidepressants such as Selective Serotonin Re-uptake Inhibitors (SSRIs), your doctor might consider changing the dose of your medicine (see also section 2 Other medicines and Nortriptyline tablets and section 3),

If you have excessive fever (hyperpyrexia).

If you are going to have electroconvulsive therapy (electric shock),

If you have had an allergic reaction to another tricyclic antidepressant in the past;

Elderly 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).

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 Tablets

Some medicines may affect the action of other medicines and this can sometimes cause serious side effects.

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

- Valproic acid (medicine used for the treatment of epilepsy and bipolar disorder)
- 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 tablets (see section 2 Do not take nortritptyline tablets)
- adrenaline, ephedrine, isoprenaline, noradrenaline, phenylephrine and phenylpropanolamine (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 Parkinsons disease and gastrointerstinal 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. babiturates)
- Buprenorphine. These medicines may interact with nortriptyline tablets. 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 tone, body temperature above 38°C. Contact your doctor if you experience such symptoms.
- 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)

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.

Nortriptyline tablets with Alcohol

It is not advised to drink alcohol during treatment with this medicine as it 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 breast-feeding for your child and the benefit of therapy for you.

Driving and using machines

This medicine may cause drowsiness and dizziness, especially in the beginning of the treatment. Do not drive or work with tools or machinery if you are affected.

Nortriptyline tablets contains lactose

If your doctor has told you that you have intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Nortriptyline Tablets

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

Adults

The recommended dose is 25mg three or four times daily or the dose should be taken once a day, usually at night. The dose should begin at a low level, e.g. 10 mg three or four times daily, 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 at low level (10-20 mg) and may be increased as required upto 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.

Duration of treatment

As with other medicines for the treatment of depression it may take a few weeks before you feel any improvement.

In treating depression, the duration of treatment is individual, and is usually at least 6 months. The duration of treatment is decided by your doctor.

Continue to take this medicine for as long as your doctor recommends.

The underlying illness may persist for a long time. If you stop your treatment too soon, your symptoms may return

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 noritriptyline in the blood.

Use in children and adolescents

This medicine should not be given to children or adolescents for treatment of depression. For further information please see section 2.

Method of administration

Swallow the tablets with a drink of water.

If you take more Nortriptyline tablets than you should

Contact your doctor or nearest hospital casualty department immediately. Do this even if there are no signs of discomfort or poisoning. Take the container of this medicine with you if you go to a doctor or hospital.

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.

If you forget to take Nortriptyline tablets

Take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose

If you stop taking Nortriptyline tablets

Your doctor will decide when and how to stop your treatment to avoid any unpleasant symptoms that might occur if it is stopped abruptly (e.g. headache, feeling unwell, sleeplessness and irritability). If you have any further questions on the use of this product, 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 get any of the following symptoms you should see your doctor immediately:

- 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 (Very rare side effect, may affect up to1 in 10,000 people).

- A heart problem called "prolonged QT interval" (which is shown on your electrocardiogram, ECG) (Common side effect, may affect up to 1 in 10 people).
- Bad constipation, a swollen stomach, fever and vomiting.

These symptoms may be due to parts of the intestine becoming paralysed (Rare side effect, may affect up to 1 in 1,000 people).

- Any yellowing of the skin and the white in the eyes (jaundice).
- Your liver may be affected (Rare side effect, may affect up to 1 in 1,000 people).
- 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) (Rare side effect, may affect up to 1 in 1,000 people).
- Suicidal thoughts or behaviour (Rare side effect, may affect up to 1 in 1,000 people).

Side effects listed below have been reported in the following frequencies:

Very common: may affect more than 1 in 10 people

- sleepiness/drowsiness
- shakiness of hands or other body parts
- dizziness
- headache
- irregular, hard, or rapid heartbeat
- dizziness when you stand up due to low blood pressure (orthostatic hypotension)
- dry mouth
- constipation
- nausea
- excessive sweating
- weight gain
- slurred or slow speech
- aggression
- congested nose.
- accommodation disorder of the eyes

Common: may affect up to 1 in 10 people

- confusion
- sexual disturbances (decreased sex-drive, problems with erection)
- disturbance in attention
- changes in taste
- numbness or tingling in the arms or legs
- disturbed coordination
- Blurred vision (dilated pupils)
- heart block
- fatigue
- low sodium concentration in the blood
- agitation
- urination disorders
- feeling thirsty.

Uncommon: may affect up to 1 in 100 people

- excitement, anxiety, difficulties sleeping, nightmares
- convulsions
- tinnitus
- increased blood pressure
- diarrhoea, vomiting
- skin rash, nettle rash (urticarial), swelling of the face and tongue
- difficulties passing urine
- increased production of breast milk or breast milk outflow without breast feeding
- increased pressure in the eye ball
- collapse conditions
- worsening of cardiac failure
- liver function impairment (e.g. cholestatic liver disease).

Rare: may affect up to 1 in 1,000 people

- decreased appetite
- delirium (especially in elderly patients), hallucinations (especially in patients with schizophrenia),
- abnormality in the heart's rhythm, or heartbeat pattern
- swelling of the salivary glands
- hair loss
- increased sensitivity to sunlight
- breast enlargement in men
- fever
- weight loss
- abnormal results of liver function tests.

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

- heart muscle disease
- feeling of inner restlessness and a compelling need to be in constant motion
- disorder of the peripheral nerves
- acute increase of pressure in the eye
- particular forms of abnormal heart rhythm (so called torsades de pointes)
- allergic inflammation of the lung alveoli and of the lung tissue.

Not known: frequency cannot be estimated from the available data

- absent sensation of appetite
- elevation or lowering of blood sugar levels
- paranoia
- movement disorders (involuntary movements or decreased movements)
- hypersensitivity inflammation of heart muscle
- hepatitis
- hot flush
- syndrome of inappropriate secretion of antidiuretic hormone (SIADH).

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects that affect you can help provide more information on the safety of this medicine.

5. How to Store Nortriptyline Tablets

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

- If your doctor stops your treatment, take any leftover tablets back to the pharmacy for safe disposal.
- Do not use this medicine after the expiry date which is stated on the label after EXP. qhe expiry date refers to last day of that month
- Do not throw away any medicines via waste water or house hold waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of Pack and other Information

What Nortriptyline Tablets contains

Each tablet contains 10 mg nortriptyline (as nortriptyline hydrochloride)
Each tablet contains 25mg nortriptyline (as nortriptyline hydrochloride)
The other ingredients are
Maize Starch
Lactose Monohydrate,
Magnesium stearate

What Nortriptyline tablets look like and contents of the pack

Nortriptyline 10 mg Tablets

Biconvex white round tablets, marked 10 on one side (Diameter: 5.5±0.20mm)

Nortriptyline 25 mg Tablets

Biconvex white round tablets, marked 25 on one side (Diameter: 8.0±0.20mm).

Nortriptyline tablets are available in blister packs of 7, 10, 14, 15, 20, 25, 28, 30, 40, 42, 45, 50, 56, 60, 70, 75, 80, 84, 90, 98 and 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder
RIA Generics Limited,
36 Ingleby Way, Wallington,
Surrey SM6 9LR, UK

Manufacturer:
RIA Generics Limited
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If you would like this leaflet in a different format please contact the marketing authorisation holder listed above.

If you would like to have any further information or want to report any side effects, please email at info@riagenerics.com.

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