Nortriptyline is a medicine used to treat major depression in adults.

Do not take Nortriptyline if:
• you are allergic (hypersensitive) to Nortriptyline or any of the other ingredients of this medicine (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 heart failure.
• you have heart disease.
• you are taking or have stopped taking in 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 a history of seizures (fitting).
• you have difficulty in changing sexual performance.
• you are going to have electroconvulsive therapy.

Warnings and precautions
Talk to your doctor or pharmacist before taking Nortriptyline if:
• you feel irritable or aggressive.
• you are agitated, overactive, or suffer from schizophrenia.
• you have heart disease.
• you have a thyroid condition or receive thyroid medication.

How to take Nortriptyline
• you have high blood pressure in the eyes (glaucoma).
• you have an enlarged prostate.
• you are going to have electroconvulsive therapy (electrical shock).
• you may also have an allergy to another tricyclic antidepressant in the past.
• you have had an allergic reaction to another tricyclic antidepressant in the past.
• you have a history of epilepsy.
• you have bipolar disorder; some patients may enter into a manic phase in which the symptoms of the manic phase (e.g. narrowing of the gastral outlet) and nausea can occur.
• you have had an allergic reaction to another tricyclic antidepressant in the past.
• you have anemia, or an operation - tell your doctor as it may be necessary to stop the treatment with Nortriptyline before you will be given any substances.
• you have had an allergic reaction to another tricyclic antidepressant in the past.
• you have had an allergic reaction to another tricyclic antidepressant in the past.
• you have diabetic or other diabetes.
• you have had any change in your blood counts.
• you have a history of seizures (fitting).

How to take Nortriptyline
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, such as:
• any monoamine oxidase inhibitors (MAOIs) e.g. moclobemide, phenelzine, isocarboxazid or tranylcypromine (used to treat depression) or selegiline (used to treat Parkinson's disease). These should not be taken for at least 2 weeks before Nortriptyline (section 2 Do not Take Nortriptyline!)
• any medicines that are used to treat Parkinson's disease, or other neurological conditions (e.g. dopamine, reserpine, levodopa, cocaethylene, and levodopa, dopamine, and cocaethylene). (Rare side effect, may affect up to 1 in 1,000 people). (Rare side effect, may affect up to 1 in 100,000 people).

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:
• Abnormalities in blood pressure, vision, and pain.

You should immediately have an eye examination before the treatment with this medicine can continue. This condition may be a sign of acute glaucoma. (Very rare side effect, may affect up to 1 in 100,000 people).
• Blood pressure, blood clotting, and blood flow.

These symptoms may be due to the drowsiness of the intake becoming paralysed. (Rare side effect, may affect up to 1 in 10,000 people).

Appetite and weight, appetite and food.
• Appetite and weight.

You may have symptoms of weight loss, nausea, and vomiting. (Rare side effect, may affect up to 1 in 10,000 people).

Breathing, breathing.
• Breathing difficulties.

This can be the first sign that your bone or lung marrow may be affected. (Rare side effect, may affect up to 1 in 10,000 people).

Effects on the blood could be a decrease in the number of red cells (which carry oxygen round the body), white blood cells (which help to fight infection) and platelets (which help with clotting). (Rare side effect, may affect up to 1 in 10,000 people).
The following side effects have also been reported:

**Very common:** may affect more than 1 in 10 people
- tremor/blotchiness of hands or other body parts
- dizziness
- accommodation disorder of the eyes
- headache
- irregular or heavy heartbeats
- dry mouth
- constipation
- nausea (feeling sick)
- excessive sweating
- weight gain
- aggression
- blooded nose

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

**Uncommon:** may affect up to 1 in 100 people
- changes in sleep patterns (including nightmares)
- numbness
- high blood pressure
- anxiety
- loss of appetite
- convulsions (body muscles contract and relax rapidly and repeatedly, resulting in an uncontrollable shaking of the body)
- faintness (ringing sounds in ear)
- increased blood pressure
- diarrhoea
- vomiting
- skin rash, nettle rash (urticaria)
- swelling of the face
- an enlarged or swollen tongue
- increased production or surplus of breast milk without breast feeding
- increased pressure in the eye ball
- collapse conditions
- worsening of cardiac failure
- changes in sexual performance
- liver function impairment (e.g. chronic liver disease and jaundice)

**Rare:** may affect up to 1 in 1,000 people
- mouth or gum problems
- decreased appetite
- confusional states (delirium), especially in the elderly perhaps with anxiety and restlessness
- hallucinations (especially in patients with schizophrenia)
- abnormality in the heart's rhythm, or heartbeat pattern, more serious heart problems along with ringing in the ears, stomach cramps and dizziness can also occasionally occur
- swelling of the salivary glands
- increases in blood have been reported
- hair loss
- increased sensitivity to sunlight
- a rash, which may be itchy or get worse in sunlight
- enlargement of male breast tissue
- fever
- weight loss
- abnormal results of liver function tests
- withdrawal symptoms: if you suddenly stop taking the capsules, you may not be able to sleep and may feel irritable or sweaty

**Very rare:** may affect up to 1 in 10,000 people
- heart muscle disease
- abnormal heart rhythm that can lead to sudden cardiac death (so called torsades de pointes)
- feeling of inner restlessness and a compelling need to be in constant motion
- disorders of the peripheral nerves
- allergic inflammation of the lung alveoli and of the lung tissue
- alteration 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

**Not known:** frequency cannot be estimated from the available data
- changes of blood sugar levels
- pancreas
- dry eyes
- movement disorders (involuntary movements or decreased movements)
- hyper-sensitivity inflammation of heart muscle
- hepatitis
- hot flush
- syndrome of inappropriate secretion of antidiuretic hormone (SIADH)

An increased risk of bone fractures has been observed in patients taking this type of medicines.

**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 bottle, blister or carton after EXP. The expiry date refers to the last day of that month.

This medicinal product 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 Nortriptiline contains**
- The active substance is Nortriptiline hydrochloride. Each capsule contains 10 mg or 25 mg Nortriptiline hydrochloride (R).
- The other ingredients are: 10 mg and 25 mg Capsule core: Stearic acid, Lactose monohydrate, Maize starch and talc. 10 mg and 25 mg Capsule shell: Gelatin, Titanium Dioxide (E171) and CI 77891, Yellow iron oxide (E172)

**What Nortriptiline looks like and contents of the pack**
- 10 mg – Size 4 capsules with opaque yellow caps and opaque white bodies with “APO 10” with white to off-white powder.
- 25 mg – Size 2 capsules with opaque yellow caps and opaque white bodies with “APO 25” with white to off-white powder.

Nortriptiline 10 mg and 25 mg capsules are supplied in cartons containing 100 capsules or bottles containing 100 capsules.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**