PACKAGE LEAFLET: INFORMATION FOR THE USER

Nortriptyline 10 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

How does Nortriptyline work?

Nortriptyline, the active substance in Nortriptyline Tablets, is intended for the treatment of major depressive episodes in adults. In depressed patients there is often a deficiency of certain chemical substances in the brain, such as serotonin and noradrenaline. These substances are called neurotransmitters. They provide for the transferring of stimuli between nerve cells in the brain, as a result of which these nerve cells can communicate with each other. Antidepressants can rectify this deficiency and by doing so improve the patient's depressed state.

Nortriptyline is an antidepressant. This means that Nortriptyline acts against the symptoms that accompany depression, such as a depressed mood, loss of interest, mood swings during the day (a better mood in the evening than in the morning), trouble sleeping through (waking up early and not being able to go to sleep again) and weight loss**.**

2. What you need to know before you take Nortriptyline

Do not take Nortriptyline if you:

- are allergic to any of the ingredients in this medicine (listed in section 6)
- have recently had a heart attack (myocardial infarction)
- have heart rhythm disorders that are seen on an electrocardiogram (heart trace), or if you have any form of heart block or a condition of the coronary artery
- are being treated with a MAO inhibitor (monoamine oxidase inhibitors, another type of drug for depression).

MAO inhibitors are, among others, phenelzine, iproniazid, isocarboxazid, nialamide or tranylcypromine for the treatment of depression and selegiline for the treatment of Parkinson's disease.

If you have used any of these products, you must wait 14 days before you can start with Nortriptyline.
If you have used the MAO inhibitor moclobemide (for the treatment of depression), you must wait one day before you can start with Nortriptyline.

Warnings and precautions

Talk to your doctor or pharmacist before using this medicine.

Suicidal thoughts 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 thoughts may increase when you start to take drugs against depression (antidepressants) for the first time, since these medicines take time to work, usually about 2 weeks or sometimes longer.

You may be more likely to have these kinds of thoughts:
- 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 young 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 can 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.

Tell your doctor if you have any other condition or illness. Your doctor might take this into consideration. In particular, tell your doctor:

- if you have epilepsy or have ever had seizures/fits.
- If you are agitated, overactive, or suffer from schizophrenia
- if you have difficulty urinating.
- if you have an enlarged prostate.
- if you have liver conditions.
- if you have heart conditions.
- if you have thyroid problems.
- if you have glaucoma (raised pressure in the eye).
- if you are being treated for diabetes. It may be necessary to adjust your diabetes treatment when you start Nortriptyline treatment.
- if you have a mental illness (psychiatric disorder) other than depression.
- if you have to have an operation. Tell your doctor that you are taking this medicine.
- if you have low blood pressure.
- if you have a sore throat, fever and symptoms of flu in the first 10 weeks
- if you have pylorus stenosis **(narrowing of the gastric outlet)** and paralytic ileus **(blocked intestine)**
- if you have a high fever (hyperpyrexia).
- If you are taking opioids (e.g., buprenorphine). The use of these medicines together with Nortriptyline can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Nortriptyline")

Note:
Some patients with manic-depressive conditions may go through a manic phase. This is characterised by unusual and rapidly changing thoughts, exaggerated cheerfulness and excessive physical activity. In such cases it is important to consult your doctor.

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

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. Patients less than 18 years of age have an increased risk of suicide attempts, thoughts of suicide and hostility (mainly aggression, oppositional behaviour and anger) if they are treated with drugs from this therapeutic class.

Elderly

Elderly patients should be careful about a fall in blood pressure, by for example standing up quickly from a sitting or lying position sometimes accompanied by dizziness.

Other medicines and Nortriptyline

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

Extra care is needed if you are taking any of the following medicines:Monoamine oxidase inhibitors (MAO inhibitors), e.g. Moclobemide (for the treatment of depression) or selegiline (for the treatment of Parkinson's disease).

- Drugs with a stimulating action on a certain part of the nervous system (sympathicomimetics), such as adrenaline, ephedrine, isoprenaline, noradrenaline, phenylephrine, and phenylpropanolamine (present in certain sedatives and narcotic agents and drugs against a cold).
- Certain blood-pressure reducing drugs, such as guanethidine, betadine, reserpine, clonidine and methyldopa. Drugs such as Nortriptyline may counteract the antihypertensive action.
- Drugs with an inhibiting action on a certain part of the nervous system (anticholinergics). Drugs such as Nortriptyline may potentiate the effects of these medicines on the eyes, the central nervous system, the intestines and the bladder, which can lead to among other things a blockage (constipation/obstipation) or fever.
- Thioridazine (used to treat schizophrenia)
- Tramadol (painkiller)
- Opioids (e.g., buprenorphine) 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.
- Agents that suppress the central nervous system, such as alcohol or barbiturates (sleeping tablets). Nortriptyline may potentiate the effects of such agents.
- Antipsychotics (for the treatment of certain psychiatric conditions), sleeping tablets, anxiolytics (for the treatment of anxiety disorders), antihistamines (for the treatment of allergies and hay fever), as the tranquillising effect of these medicines could be potentiated.
- St. John's Wort (*Hypericum perforatum*) a herbal remedy used for depression.
- Drugs that stimulate the thyroid (thyreomimetics).

- Levodopa (a drug against Parkinson's disease). The breakdown of levodopa in the intestine is potentiated by Nortriptyline.
- Disulfiram (a drug in the treatment of alcoholism) or tramadol (for the treatment of acute and chronic moderate to severe pain).
- Treatment with ECT (electric shock therapy).
- Drugs that have a potentiating action on the serotonin system, such as other drugs for depression (selective serotonin reuptake inhibitors (SSRIs). A rare condition that is known as serotonin syndrome may develop. Symptoms may be: high fever, agitation, confusion, trembling and sudden muscle contractions.
- Antipsychotics (drugs for the treatment of a serious mental illness, characterised by phenomena such as delusions, seeing things that are not there (hallucinations) and gradual changes in personality (schizophrenia) and a mental illness in which control over one's own behaviour and actions is disturbed (psychoses). SSRIs (fluxetine, paraxetine, fluvoxamine and bupropion), beta blockers (a certain group of drugs for high blood pressure), certain heart conditions and raised ocular pressure) and drugs for heart rhythm disorders (antiarrythmics). These medicines may increase the plasma levels of Nortriptyline.
- Antipsychotics in connection with the possible risk of a reduced stimulus threshold for seizures.
- Barbiturates (sleeping tablets), oral contraceptives, rifampicin (to treat infection), phenytoin and carbamazepine (drugs for epilepsy) may reduce the plasma level of Nortriptyline. The dosage of Nortriptyline may have to be adjusted.
- Cimetidine (used in the treatment of gastric ulcer), methylphenidate (used in the treatment of hyperactivity) and calcium channel blockers (used in the treatment of high blood pressure) may increase the plasma levels of Nortriptyline. The likelihood of side effects is increased with these drugs. The dosage of Nortriptyline may have to be adjusted.
- Also tell your doctor if you are taking or have recently taken drugs that may affect heart rhythm, such as:
    - Medicines for the treatment of an irregular heartbeat (such as quinidine and sotalol)
    - Astemizole and terfenadine (for the treatment of allergies and hay fever)
    - Medicines for the treatment of certain psychiatric conditions (for example: pimozide and sertindole)
    - Cisapride (for the treatment of certain forms of indigestion)
    - Halofantrine (for the treatment of malaria)
    - Methadone (used to treat pain and for detoxification)
    - Medicines for certain heart conditions (for example: Class IA antiarrhythmics, beta blockers, or calcium channel blockers (for example: verapamil)
    - Diuretics (agents against fluid retention)
    - Antifungal medicines (to combat fungal infections), such as ketoconazole, itraconazole, fluconazole and terbinafine, may increase the plasma levels of Nortriptyline. Heart problems have occurred if used concomitantly.
- Valproic acid (a medicine for the treatment of epilepsy and bipolar disorder).

Nortriptyline with food, drink and alcohol

You can take the tablets with a glass of water. Nortriptyline can be taken with or without food.

Nortriptyline may potentiate the sedating effects of alcohol. The concomitant taking of Nortriptyline with alcohol is not advised.

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 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 medicine.

Nortriptyline 25 mg tablets contain Sunset yellow FCF (E110)

May cause allergic reactions

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.

If you have the impression that the effect of Nortriptyline is too strong or too weak, talk to your doctor or pharmacist.

Use in adults:
The usual 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 25mg tablets a day, he or she may arrange for you to have regular blood tests.

If no improvement occurs after 2 - 4 weeks of treatment with the maximum dose, you should discuss this with your doctor. If there is a satisfactory response, your doctor will continue the prescribed dosage for at least 4 weeks. Your doctor will then, in consultation with you, try to gradually reduce the dose to a maintenance dose of usually 50 - 100 mg per day.

Use in elderly patients (more than 60 years of age):
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.

Impaired kidney function
Kidney failure does not affect kinetics of nortriptyline. Hence this medicinal product can be given in usual doses to patients with kidney failure.

Impaired liver function

In the case of impaired liver function, your doctor will dose carefully based on measurements in your blood.

Use in children and young people up to 18 years of age
Nortriptyline should not be given to children or adolescents. See section 2 for more information.

Duration of the treatment

It may be a few weeks before you start to feel better. This is why you must carry on taking Nortriptyline, even if it takes some time before you feel any improvement in your situation. Never change the dose of your medicine without first consulting your doctor. You should continue taking the tablets for as long as your doctor thinks you should. If you stop too quickly, the symptoms may return. It is advised to continue with the treatment for at least 6 months after you feel better again.

If you take more Nortriptyline than you should

Doses as low as 50mg (especially in children) may lead to clinically significant symptoms.

If by mistake you have taken a tablet of Nortriptyline too many, side effects, such as drowsiness, dry mouth, dizziness or nausea, may occur or become worse.

If you think that you or someone else has taken too many Nortriptyline tablets, tell your doctor or the nearest hospital casualty department at once; do this even if there are no signs of discomfort or intoxication. Take the Nortriptyline pack with you when you go to a doctor or hospital.

Symptoms of overdose may be:
- Drowsiness or over-excitement
- Agitation and hallucinations
- Loss of consciousness
- Respiratory problems, blue colouration of the skin
- Dilation of the pupil
- Seizures/fits (convulsions)
- Heart conditions, including heart rhythm disorders (seen in an ECG, an investigation to assess how the heart is functioning)
- Lowered blood pressure, weak pulse, pallor
- Metabolism disorders
- Urine retained in the bladder due to disturbed emptying of the bladder (urinary retention)
- Dry mucosa (e.g. of the throat or tongue)
- Reduced bowel movements (which can lead to obstruction (constipation)
- Fever
- Coma

Confusion, agitation, hallucinations and impaired fine motor skills are possible on waking.

If you forget to take Nortriptyline

Do not take a double dose to make up for a forgotten dose.

If you stop taking Nortriptyline

You must only stop taking Nortriptyline if your doctor decides this.
The treatment preferably continues up to 4 to 6 months after the symptoms have disappeared.

The treatment should not be stopped suddenly. The dose should be reduced gradually over a week or more. Although antidepressants are not addictive, stopping the treatment abruptly after

using for a long time may cause nausea, headache, feeling unwell (malaise), irritability and insomnia. The treatment with Nortriptyline should therefore not be stopped suddenly. The dose should be reduced gradually over a week or more.

If you have any other questions about using this medicine, contact your doctor or pharmacist.

4. Possible side effects

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

Because depressed patients may have a number of symptoms that look like the side effects of antidepressants, it is often difficult to establish whether the symptoms are a result of the depression or are caused by the medicine for the treatment of the depression.

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*
- involuntary, rhythmic contractions of muscles, including the muscles that control eye movements, agitation, hallucinations, coma, excessive sweating, tremor, exaggerated reflexes, increased muscle tension, body temperature higher than 38 °C. (signs of serotonin syndrome, a potentially life-threatening condition). (signs of serotonin syndrome, a potentially life-threatening condition).

* There have been reports of people having thoughts or behaviors of self-harm or suicidal tendencies while taking Nortriptyline or soon after treatment with Nortriptyline (see section 2 “Warnings and precautions”).

Very rare (may affect up to 1 in 10,000 people):
- intraocular pressure elevation usually shows no signs or symptoms, but it is a significant risk factor for glaucoma. 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.

The following side effects have also been reported:

<u>Very common (may affect more than 1 in 10 people)</u>
- shaking (tremor), dizziness, headache
- disorder in the adjustment to see at a distance (accommodation disorder that makes objects appear blurry)
- palpitations, rapid heart rate (tachycardia)
- dry mouth, obstruction (constipation), nausea
- excessive sweating
- weight gain, blocked nose, aggression

<u>Common (may affect up to 1 in 10 people)</u>
- confusion, reduced interest in intimacy (reduced libido)

- impaired attention, impaired taste, feeling of pins and needles, itching or tingling without there being any reason for this (paraesthesia), coordination problems for example gait abnormality (ataxia)
- dilation of the pupils (mydriasis)
- certain disturbance in cardiac conduction, leading to rhythm disorders (atrioventricular block), conduction disorders
- erectile dysfunction
- fatigue
- feeling thirst
- weight gain
- heart abnormalities seen as changes in the electrocardiogram (ECG)
- dizziness when standing up due to low blood pressure (orthostatic hypotension)
- problems urinating (increased or decreased)
- low sodium concentration in blood

Uncommon (may affect up to 1 in 100 people)
- (mild form of) exaggerated hyper-alertness accompanied by having a lot of energy ((hypo) mania), anxiety, insomnia, nightmares
- seizures or fits (convulsions)
- ringing in the ears (tinnitus)
- collapse conditions
- worsening of cardiac failure
- high blood pressure (hypertension)
- diarrhoea, vomiting, accumulation of fluid in the tongue (tongue oedema)
- liver problems including jaundice
- rash, skin rash with intense itching and forming of lumps (urticaria), accumulation of fluid in the face (facial oedema)
- urine remaining in the bladder as a result of impaired emptying of the bladder (urinary retention)
- increased production or outflow of breast milk without breast feeding

Rare (may affect up to 1 in 1,000 people)
- reduced appetite
- acute confusion (delirium) in older patients, delusions (hallucinations)
- deviation in heart rhythm or heart rate pattern
- enlarged salivary glands
- baldness (alopecia)
- sensitivity to light (photosensitivity reaction)
- development of breasts in men (gynaecomastia)
- fever
- weight loss
- feeling of restlessness (akathisia), involuntary movement (dyskinesia)
- abnormal liver function test, raised values of certain liver enzymes in the blood

Very rare (may affect upto 1 in 10,000 people)
- increased pressure in the eye
- abnormal heart rhythm that can lead to sudden cardiac death (so called torsades de pointes)
- heart muscle disease
- allergic inflammation of the lung alveoli and of the lung tissue

Not known (frequency cannot be estimated from the available data)
- changes in blood sugar levels
- water retention and reduction in salt levels (sodium levels) in the blood (inappropriate antidiuretic hormone secretion (SIADH))
- movement disorders (involuntary movements or decreased movements)
- over-excitement (agitation), restlessness, aggression, delusions, orgasm disorders in women, increased interest in intimacy (increased libido), disorientation

- stoppage of bile flow (cholestasis)
- hyersensitivity inflammation of heart muscle
- increased in body temperature
- hepatitis

In patients who use this sort of drug a higher chance of broken bones has been seen.

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, 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 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.

Do not use this medicine after the expiry date which is stated on the blister, carton and 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 tablets contain

- The active ingredient is nortriptyline (as hydrochloride).

Nortriptyline 10 mg film-coated tablets
Each film-coated tablet contains 10 mg nortriptyline (as hydrochloride).

Nortriptyline 25 mg film-coated tablets
Each film-coated tablet contains 25 mg nortriptyline (as hydrochloride).

Nortriptyline 50 mg film-coated tablets
Each film-coated tablet contains 50 mg nortriptyline (as hydrochloride).

-The other ingredients are

Tablet core: lactose monohydrate, maize starch, calcium hydrogen phosphate (E 341), magnesium stearate (E 470b).

Tablet film-coat:
Nortriptyline 10 mg and 50 mg film-coated tablets: Hypromellose (E 464), glycerol (E 422).
Nortriptyline 25 mg film-coated tablets: Hypromellose (E 464), glycerol (E 422), sunset yellow FCF aluminum lake (E 110)

What Nortriptyline looks like and contents of the pack

Nortriptyline 10 mg film-coated tablets
White to off-white colored, round, biconvex, film-coated tablets debossed with 'NT' on one face and other face plain with an approximate diameter of 5.60 mm.

Nortriptyline 25 mg film-coated tablets
Orange colored, round, biconvex, film-coated tablets debossed with 'N' and 'T' on either side of breakline on one face and other face plain with an approximate diameter of 8.10 mm.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Nortriptyline 50 mg film-coated tablets
White to off-white colored, round, biconvex, film-coated tablets debossed with 'N50' on one face and other face plain with an approximate diameter of 10.10 mm.

Alu-Alu and Alu-PVC/PE/PVDC blister pack:
Pack size: 10, 14, 15, 20, 24, 25, 28, 30, 50, 56, 100 and 150 film-coated tablets.

HDPE bottle pack:
Pack size: 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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If you would like a leaflet with larger text, please contact +44 (0)203 384 7188.