Package leaflet: Information for the user

Nortriptyline 10mg & 25mg 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 film-coated tablets are and what they are used for

Nortriptyline film-coated tablets contain the active ingredient nortriptyline hydrochloride, which is a tricyclic antidepressant.
Nortriptyline tablets are indicated for the treatment of major depressive episodes in adults.

2. What you need to know before you take Nortriptyline film-coated tablets

You should not take Nortriptyline film-coated tablets until you are sure it is safe for you to do so.
Nortriptyline film-coated tablets are for adults only.

Do not take Nortriptyline film-coated tablets:
- If you are allergic to nortriptyline hydrochloride or any of the other ingredients of this medicine (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;
- If you have had a recent heart attack or heartbeat disorder;
- If you are taking, or have taken in the last two weeks, monoamine oxidase inhibitors (another type of antidepressant e.g. phenelzine, isocarboxazid or tranylcypromine);
- you have to stop treatment with Nortriptyline tablets and wait for 14 days before you start treatment with a monoamine oxidase inhibitor.

Warnings and precautions
Talk to your doctor or pharmacist before taking Nortriptyline film-coated tablets
- If you feel suicidal or aggressive - tell your doctor;
- If you are agitated, overactive, or suffer from schizophrenia or another mental illness;
- If you have heart disease or low blood pressure;
- 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 or difficulty passing urine;
- If you are going to have electroconvulsive therapy (electric shock);
- If you are diabetic; It may be necessary to adjust your diabetes therapy when you start Nortriptyline Tablets
- If you are going to receive an anaesthetic, e.g. for an operation – tell your doctor; You may need to stop taking Nortriptyline Tablets several days before the operation. If your doctor tells you to carry on taking Nortriptyline Tablets, make sure the doctors treating you in the hospital know that you are on Nortriptyline Tablets
- If you have had an allergic reaction to another tricyclic antide pressant in the past;

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 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 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.

If any of the above apply to you, tell your doctor or pharmacist.

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.

Taking other medicines and Nortriptyline film-coated tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take, any other medicines, including medicines obtained without a prescription.

The following medicines may interact with your Nortriptyline film-coated tablets:

- 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). Tell your doctor or pharmacist if you are taking them now or have taken them in the last 2 weeks. These should not be taken at the same time as Nortriptyline film-coated tablets (see section 2 Do not take Nortriptyline film-coated tablets)
- adrenaline, ephedrine, isoprenaline, noradrenaline, phenyle phrine 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)
- 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)
- 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
- valproic acid (medicine used for the treatment of epilepsy and bipolar disorder).

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.

Taking Nortriptyline film-coated tablets with alcohol

You should not drink alcohol while you are being treated with Nortriptyline film-coated 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 or pharmacist 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.

If you are breast-feeding, ask your doctor or pharmacist for advice before taking Nortriptyline film-coated tablets.

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 tablets 10mg and 25mg 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 tablets 25mg contain sunset yellow (E110)
Sunset yellow (E110) may cause allergic reactions.

3. How to take Nortriptyline film-coated tablets

Always take this medicine exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

Dosage
Adults:
The usual 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.

The elderly:
The usual 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.

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

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. Patients under 18 have an increased risk of suicide attempts, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they are treated with drugs of this class.

Duration of treatment
It may take a few weeks before you feel any improvement.
Following remission, maintenance treatment may be needed longer term. This should be at the lowest dose that stops the symptoms of depression coming back.
Nortriptyline film-coated tablets are for oral use
The score line on the 25mg tablet is only there to help you break the tablet if you have difficulty swallowing it whole.

If you take more Nortriptyline film-coated tablets than you should
Go to the nearest casualty department or contact your doctor immediately. Take the tablet carton with you. An overdose can be very dangerous.

If you forget to take Nortriptyline film-coated 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 taking Nortriptyline film-coated 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, this medicine 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.

Also tell your doctor immediately if you experience any of the following:

- 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 to 1 in 10,000 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)

The following side effects have been reported:

Very common (may affect more than 1 in 10 people)
Shaking (tremor), dizziness, headache, dry mouth, nausea, sweating, flushing, constipation, trouble adjusting to see including blurred vision (accommodation disorder), a drop in blood pressure for example when standing up quickly from a sitting or lying position sometimes accompanied by dizziness (orthostatic hypotension) and irregular or heavy heart beat.

Common (may affect up to 1 in 10 people)
Fatigue, weakness, weight gain, abnormalities of the ECG (electrocardiogram (ECG)), dysfunction of the ventricles of the heart (ventricular dysfunction), disorders in the conduction of the heart leading to arrythmias (atrioventricular block), conduction disorders of the heart. High or low blood pressure. Difficulties concentrating, taste disturbances, sensation of tickling, itching or tingling without any prompts (paraesthesia), coordination problems e.g. drunken gait (ataxia), dilation of the pupils (mydriasis), strange body movements. Erectile dysfunction, decreased sex drive (libido).

Uncommon (may affect up to 1 in 100 people)
Ringing in the ears (tinnitus), fits or seizures (convulsions), numbness, increased pressure in the eye (intraocular pressure), diarrhoea, vomiting, fluid accumulation in the tongue (tongue oedema), problems urinating (urinary retention), rash, skin rash with intense itching and hives (urticaria), fluid retention in the face (facial oedema), increased blood pressure (hypertension), (lighter form of) excessive cheerfulness associated with having a lot of energy ((hypo)mania), anxiety, insomnia, changes in sleep pattern including nightmares.

Rare (may affect up to 1 in 1,000 people)
Weight gain or loss, diarrhoea, stomach cramps, abnormal liver function test, increased blood liver enzymes, disturbances in heart rhythm (arrhythmia), decrease in blood-forming cells in the bone marrow (bone marrow depression), very serious blood disorder (lack of white blood cells) associated with sudden high fever, severe sore throat and sores in the mouth (agranulocytosis), blood disorder (lack of white blood cells) associated elevated susceptibility to infections (leucopenia), blood abnormalities (low platelet count) associated with bruising and bleeding (thrombocytopenia), increase salivary glands, loss of bowel movement (paralytic ileus), baldness (alopecia), photosensitivity, decreased appetite, fever, peculiar taste, mouth or gum problems, jaundice, breast development in men (gynecomastia), changes in sexual performance, clumsiness, irritability, acute confusion (delirium) especially in elderly patients, hallucinations in schizophrenic patients.

Very rare (may affect up to 1 in 10,000 people)
Changes in blood sugar, swelling of the breasts (men and women) and increased/inappropriate milk production (galactorrhoea), swelling of testicles.

Not known (frequency cannot be estimated from the available data)
Water retention and reduction of salt levels (sodium glucose) in the blood. Syndrome of inappropriate antidiuretic hormone secretion (SIADH), cholestasis, suicidal ideation and self-harming behaviours, agitation, restlessness, aggressive outbursts, delusions, orgasmic disorder in women, increased libido (sexual desire), disorientation and higher risk of fractures.

There are reports of people who have suicidal or self-harming thoughts or behaviour while taking Nortriptyline tablets or shortly after treatment with Nortriptyline tablets (see Section 2).

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 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 film-coated 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 label or 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 any medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Nortriptyline film-coated tablets contain
The active substance is nortriptyline hydrochloride. Each tablet contains the equivalent of 10mg or 25mg nortriptyline base.

The other ingredients are:
Tablets 10mg: Lactose Monohydrate, Calcium Hydrogen Phosphate, Starch Pregelatinized, Magnesium Stearate. Coating: Hypromellose (E464), Macrogol 8000, Macrogol 400 (E1521).

Tablets 25mg: Lactose Monohydrate, Calcium Hydrogen Phospha-te, Starch Pregelatinized, Magnesium Stearate. Coating: Hypromel-lose (E464), Macrogol 8000, Macrogol 400 (E1521), Sunset Yellow FCF Aluminum Lake (E110).

What Nortriptyline film-coated tablets look like and contents of the pack
Nortriptyline 10 mg film-coated tablets are presented as white, round, biconvex film-coated tablets debossed with “10” on one side and 5.5 mm in diameter

Nortriptyline 25 mg film-coated tablets are presented as orange, round, biconvex film-coated tablets with score line on one side, debossed with “25” on the other side and 8 mm in diameter.

Alu/PVC-PVCD Blister or HDPE bottles containing 30 or 100 tablets.

Not all pack sizes may be marketed.

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