Package leaflet: Information for the user

Nortriptyline 10 mg Film-coated Tablets
Nortriptyline 25 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 Tablets are and what they are used for

Nortriptyline tablets contain the active ingredient nortriptyline hydrochloride, which is known as a tricyclic antidepressant. Nortriptyline tablets relieve the symptoms of depression.

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

You should not take Nortriptyline Tablets until you are sure it is safe for you to do so. Nortriptyline Tablets are for adults only.

Do not take Nortriptyline Tablets if:
- you are allergic to nortriptyline or any of the other ingredients of this medicine (listed 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
- you are taking, or have taken in the last two weeks, monoamine oxidase inhibitors (another type of antidepressant)

Warnings and precautions
Talk to your doctor or pharmacist before taking Nortriptyline Tablets, if:
- you feel suicidal or aggressive (see the section below for more information)
- you are agitated, overactive, or suffer from schizophrenia or another mental illness
- you have heart disease or low blood pressure
- you have a cardiac condition called Brugada syndrome
- you have severe liver disease
- you have a thyroid condition

- you have a history of convulsions/seizures (epilepsy)
- you have high pressure in the eyes (raised intra-ocular pressure) or glaucoma
- you have an enlarged prostate
- you have trouble urinating (urinary retention)
- you are being treated for diabetes. It may be necessary to adjust your diabetes therapy when you start Nortriptyline Tablets
- you are going to receive an anaesthetic, e.g. for an operation – discuss this with your GP. You may need to stop taking Nortriptyline Tablets several days before the operation. If your GP tells you to carry on taking Nortriptyline Tablets, make sure the doctors treating you in the hospital know that you are on Nortriptyline Tablets
- you have had an allergic reaction to another tricyclic antidepressant in the past
- you are pregnant, think you might be pregnant or planning to become pregnant or breast-feeding you should not take Nortriptyline Tablets unless your doctor tells you to
- you have a sore throat, fever and symptoms of influenza in the first 10 weeks of treatment
- you have excessive fever (hyperpyrexia)
- you are being treated for pain or opioid substitution. The use of Nortriptyline Tablets with buprenorphine can lead to serotonin syndrome, a potentially life-threatening condition.

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.

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 or have recently taken any other medicines, such as:

- monoamine oxidase inhibitors – 'MAOIs' (phenelzine (Nardil), tranylcypromine, isocarboxazid). **Tell your doctor or pharmacist if you are taking them now or have taken them in the last 2 weeks**
- anti-depressants such as citalopram, escitalopram, duloxetine, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine, trimipramine, or buprenorphine used in the treatment of pain or opioid substitution therapy. These medicine may interact with Nortriptyline Tablets 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.**
- medicines for your heart or for high blood pressure including guanethidine, debrisoquine, bethanidine, clonidine and methyldopa
- moclobemlde, you must stop this at least 24 hours before starting nortriptyline

- adrenaline-like drugs including ephedrine, isoprenaline, phenylephrine and phenylpropanolamine – these drugs may be in cold remedies
- barbiturates (used for anxiety or to make you feel sleepy)
- cimetidine (for heartburn and ulcers)
- other medicines including other antidepressants, medicines for other neurological or mental illness or medicines for bowel complaints, breathing difficulties, epilepsy, bronchitis, glaucoma or prostate trouble
- levothyroxine (used to treat thyroid conditions)
- antifungal medications (e.g. fluconazole and terbinafine)
- antihistamines (e.g. astemizole or terfenadine)
- tramadol (painkiller)
- Valproic acid (medicine used for the treatment of epilepsy and bipolar disorder).

It may still be all right for you to be given Nortriptyline Tablets. Your doctor will be able to decide what is suitable for you.

Nortriptyline Tablets with food, drink and alcohol
You should not drink alcohol while you are being treated with Nortriptyline Tablets. You may find that you get more drunk or feel more depressed.

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.

The safety of nortriptyline for use during pregnancy has not been established.

The amount of nortriptyline in breast milk is low, and no adverse effects on breast-fed infants of mothers taking nortriptyline have been reported. However you should discuss the fact that you are breast-feeding with your doctor if you are prescribed nortriptyline.

Driving and using machines
Nortriptyline Tablets may affect alertness. Use caution when driving or operating heavy machinery until you are 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 contain 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 Tablets

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

The recommended dose is:
Adults:
- The usual adult dose is 25 mg three or four times daily or the dose may be given once a day. The dose should begin at a low level, 25 mg, 2-3 times daily, for example and be increased gradually as required. The maximum dose is 150 mg per day.
- If there is a satisfactory response, your doctor will continue Nortriptyline Tablets for at least 4 weeks. Your doctor will work with you to try to reduce to a maintenance dose of 100 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.

- Do not suddenly stop taking the tablets. Your doctor will tell you how to cut them down gradually.

Elderly:

The usual dose is 30 to 50 mg a day in divided doses. Treatment may start with 10 mg once or twice a day. If necessary your doctor may increase your dose by 10 mg every other day. If you require a dose of 50 mg or more, your doctor will arrange for your to have a recording of your heart (ECG) and blood tests. The additional tablets should be taken in the morning.

Use in children and adolescents
The use of Nortriptyline Tablets in children and adolescents is not recommended.
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.

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

If you forget to take Nortriptyline Tablets
If you forget to take a dose, take one as soon as you remember. Do not take a double dose to make up for a forgotten dose. If you have missed several doses, tell your doctor.

If you stop taking Nortriptyline 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.

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

- serious heart problems along with ringing in the ears, stomach cramps and clumsiness
- swelling of ankles and in severe cases of the face and tongue
- alterations in brain function (including perhaps seizures)
- blood disorders along with changes in blood sugar level
- swelling of breasts and testicles in men and increase in breast size and spontaneous lactation in women
- alteration of your liver function (shown by blood tests) due to swelling and damage to liver cells
- flu like symptoms including sore throat if occurring during the first 10 weeks of treatment.

The following side effects have also 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/inapropriate 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 and low sodium concentration in the blood. Brugada Syndrome (unmasking) (symptoms may include very fast heartbeat, dizziness, fainting, seizures). Tell your doctor straight away if you get these symptoms.
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: HPRA Pharmacovigilance; Website: www.hpra.ie.
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.
This medicine does not require any special storage conditions.
Do not use this medicine after the expiry date which is stated on the carton, bottle and blister after EXP. The expiry date refers to the last day of that month.
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 substance is nortriptyline hydrochloride.

Each 10 mg tablet contains nortriptyline hydrochloride, equivalent to10 mg nortriptyline.
Each 25 mg tablet contains nortriptyline hydrochloride, equivalent to 25 mg nortriptyline.

- The other ingredients are:

Lactose monohydrate, maize starch, microcrystalline cellulose, magnesium stearate, hypromellose E6, titanium dioxide, macrogol 6000.

What Nortriptyline Tablets look like and contents of the pack

- Nortriptyline 10 mg Tablets are white, round shaped, film-coated tablets debossed “10” on one side with a diameter of 5.55 mm.
- Nortriptyline 25 mg Tablets are white round shaped, film-coated tablets, debossed “25” on one side with a diameter of 8.00 mm.

Nortriptyline Tablets are available in ALU-PVC/PVDC Blisters in packs of 100 tablets (10 x blisters of 10 tablets per blister). HDPE containers containing 100 or 500 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Pharmafile Limited, Medici House, Unit 2, Ashbourne Manufacturing Park, Ashbourne, Co. Meath, Ireland.

Manufacturer
Medicofarma S.A., ul. Tarnobrzeska 13, 26-613 Radom, Poland

This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom:	Nortriptyline 10 & 25 mg Film-coated Tablets
Ireland:	Nortriptyline 10 & 25 mg Film-coated Tablets

This leaflet was last revised in 02/2024