Package Leaflet: Information for the user

Nortriptyline Chanelle Medical 10 mg Film-Coated Tablets
Nortriptyline Chanelle Medical 25 mg Film-Coated Tablets

nortriptyline (as hydrochloride)

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.

The name of this medicine is Nortriptyline Chanelle Medical 10 mg/25 mg Film-Coated Tablets.

In the rest of the leaflet Nortriptyline Chanelle Medical 10 mg/25 mg Film-Coated Tablet is called Nortriptyline film-coated tablets.

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 film-coated tablets is 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 tablets until you are sure it is safe for you to do so. Nortriptyline 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 (listed 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 (myocardial infarction);
- If you have heart arrhythmias seen on an electrocardiogram (ECG), or if you have any kind of heart block or a coronary artery disease,
- If you have severe liver disease;
- If you are agitated, overactive, or suffer from schizophrenia or another mental illness;
- If you are taking, or have taken in the last two weeks, monoamine oxidase inhibitors another

type of antidepressant include. phenelzine, isocarboxazid, nialamide or tranylcypromine for the treatment of depression and selegiline for the treatment of Parkinson's disease.

you have to stop treatment with Nortriptyline tablets and wait for 14 days before you start treatment with a monoamine oxidase inhibitor.

If you have taken the MAO inhibitor moclobemide (used to treat depression), you should: wait one day before you can start Nortriptyline Tablets

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 severe liver disease;
- 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 in 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 antidepressant in the past;
- If you are being treated with buprenorphine (an opioid medicine). The use of Nortriptyline Tablets with buprenorphine can lead to serotonin syndrome, a potentially life-threatening condition (see Other medicines and Nortriptyline film-coated tablets).
- if you have a sore throat, fever and symptoms of influenza during treatment.
- if you have an excessive fever (hyperpyrexia).

Caution:
Some patients with manic-depressive illness may go through a manic phase. This is characterized by unusual and rapidly changing thoughts, exaggerated cheerfulness and excessive physical activity. In such cases it is important to contact 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.

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.

Patients younger than 18 years have an increased risk of suicide attempts, suicidal thoughts and hostility (mainly aggression, oppositional behaviour and anger) when treated with medicines from this therapeutic class.

Elderly
Elderly patients should watch out for a drop in blood pressure, for example by getting up from a chair quickly sitting or lying position sometimes accompanied by dizziness.

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 tablets (see section 2 Do not take nortritptyline tablets)
- buprenorphine (a type of opioid medicine). This 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.**
- Substances with a stimulating effect on a certain part of the nervous system (sympathomimetics), such as 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

- Substances with an inhibitory effect on a certain part of the nervous system (anticholinergic) drugs such as certain medicines to treat Parkinsons disease and gastrointerstinaldisorders (e.g. atropine, hyoscyamine), Nortriptyline Tablets may reduce the effects of these drugs on the eyes, central nervous system, gut and bladder, which can lead to under other constipation (constipation/constipation) or fever.
- thioridazine (used to treat schizophrenia)
- Levodopa (medicine against Parkinson's disease). The breakdown of levodopa in the gut is reinforced by Nortriptyline
- Disulfiram (used to treat alcoholism)
- tramadol (painkiller)
- sedatives (e.g. babiturates), oral contraceptives, phenytoin and carbamazepine (medicines for epilepsy) may decrease the plasma level of Nortriptalyine. The dose of Nortriptalyine should be may be adjusted.
- 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)
- calcium channel blockers (used to treat a high blood pressure) may increase the plasma level of Nortriptyline. The chance of side effects is increased by these drugs. The dose of Nortriptyline may need to be amended.
- 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)
- Medicines for certain heart conditions (e.g. class IA antiarrhythmics)
- beta blockers, or calcium channel blockers (eg verapamil)).
- methadone (used to treat pain and for detoxification)
- diuretics (“water tablets” e.g. furosemide)
- Antifungal medicines (to fight fungal infections), such as fluconazole, terbinafine, ketoconazole, and itraconazole may increase the plasma level of Nortriptalyine. Heart problems are occurred with concomitant use.

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 Tablets with alcohol

You should not drink alcohol while you are being treated with Nortriptyline 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 film-coated tablets affect your ability to drive or use machines, tell your doctor immediately.

Nortriptyline film-coated 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.

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 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.

The elderly:
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 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 noritriptyline 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.

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 accidentally take too much Nortriptyline tablet, side effects, such as such as drowsiness, dry mouth, dizziness or nausea develop or worsen.

If you think you or someone else has taken too much Nortriptyline, take it immediately contact your doctor or the nearest hospital emergency department. Do this even if there are no signs of discomfort or poisoning. Take Nortriptyline pack with you when you go to a doctor or hospital.

Symptoms of an overdose may include:
- Drowsiness or excitement
- Agitation and hallucinations
- Unconsciousness
- Difficulty in breathing, blue discoloration of the skin
- Dilation of the pupil
- Convulsions
- Cardiac disorders, including cardiac arrhythmias (seen during an ECG; an examination to evaluate how the heart is functioning)
- Decreased blood pressure, weak pulse, pallor
- Disturbances of the metabolism
- Retention of urine in the bladder due to impaired bladder emptying (urinary retention)
- Dry mucous membranes (e.g. of the throat or tongue)
- Decreased bowel movements (which can lead to constipation)
- Fever
- Coma

Confusion, agitation, hallucinations and impaired fine motor skills are possible upon awakening.

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.
The dose should be reduced gradually for a week or longer. Although antidepressants are not addictive, abruptly breaking off the treatment after long-term use nausea, headache, feeling unwell (malaise), irritability and cause insomnia. The treatment with Nortriptyline should therefore not be taken all at once ended. The dose should be reduced gradually over a week or longer.

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 to1 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 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).

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, aggressive outbursts 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: 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 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 blister, carton or 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 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 (as hydrochloride).

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

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

The other ingredients are:
Lactose monohydrate (58.42 mg per 10 mg film-coated tablet **or** 146.05 mg per 25 mg film-coated tablet)
Pre-gelatinised starch
Silica colloidal anhydrous
Magnesium stearate

Coating (Opadry white):
Hypromellose – E464
Titanium dioxide – E171
Macrogol – E1521.

What Nortriptyline film-coated tablets look like and contents of the pack

Nortriptyline 10 mg film-coated tablets are white, film-coated, circular tablets, with "1" on one side and "C" on the other side.

Nortriptyline 25 mg film-coated tablets are white, film-coated, circular tablets, with "C2" on one side and plain on the other side.

PVC/PVDC blister packs each pack contains 25 film-coated tablets or plastic bottles containing 500 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Chanelle Medical
Dublin Road,
Loughrea,
Co. Galway,
Ireland.

Manufacturers:
Chanelle Medical
Dublin Road, Loughrea, Co. Galway,
Ireland.

Pharmadox Healthcare Ltd.
KW20A Kordin Industrial Park,
Paola PLA3000,
MALTA.

This leaflet was last revised in June 2022