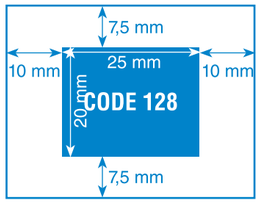
420 mm
210 mm
35 mm
280 mm

Package leaflet: Information for the user

Nortriptyline 10 mg Capsules
Nortriptyline 25 mg Capsules

Warning – Thoughts of self- harm and suicidal behaviour – see section 2

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.



Nortriptyline hydrochloride (referred to as Nortriptyline in the remainder of the leaflet)

WHAT IS IN THIS LEAFLET
1. What Nortriptyline is and what it is used for
2. What you need to know before you take Nortriptyline
3. How to take Nortriptyline
4. Possible side effects
5. How to store Nortriptyline
6. Contents of the pack and other information

1. WHAT NORTRIPTYLINE IS AND WHAT IT IS USED FOR

Nortriptyline belongs to a class of medicines called tricyclic antidepressants. Nortriptyline is a medicine used to treat major depression in adults.

As with many other kinds of medications and treatments, we don't know for certain how antidepressants work. We do know that they affect the activity of certain chemicals in our brains. These are called neurotransmitters, and pass signals from one brain cell to another. The neurotransmitters most affected by antidepressants are serotonin and noradrenaline. However, research suggests that antidepressants work on the brain in multiple ways that go beyond simple chemical reactions. This research suggests that they:
- influence how the body responds to stress
- improve our negative thinking
- stop or even reverse damage to brain cells

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NORTRIPTYLINE

Do not take Nortriptyline if:
- you are allergic (hypersensitive) 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, heart block or coronary artery 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 to stop treatment with Nortriptyline Capsules 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 if:
- you feel **suicidal** or **aggressive**;
- you are **agitated, overactive,** or suffer from **schizophrenia**;
- you have **heart disease**;
- you have a **thyroid** condition or receive thyroid medication;
- you have a history of **epilepsy**;
- you have high pressure in the eyes **(glaucoma)**;
- you have an enlarged **prostate**;
- you are going to have electroconvulsive therapy **(electric shock)**;
- you are **diabetic** as you might need an adjustment of your antidiabetic medicine;
- you are going to receive an **anaesthetic**, e.g. for an operation - tell your doctor as it might be necessary to stop the treatment with Nortriptyline before you are given anaesthetics;
- you have had an **allergic reaction** to another tricyclic antidepressant in the past as cross sensitivity may occur.
- you have difficulty in **passing urine**;
- you have **bipolar disorder;** as some patients may enter into a manic phase
- you have pylorus stenosis **(narrowing of the gastric outlet)** and paralytic ileus **(blocked intestine)**
- you have excessive fever **(hyperpyrexia)**;
- you are elderly as you are more likely to suffer from certain side effects, such as dizziness when you stand up due to low blood pressure (see also section 4 Possible side effects).
- you have severe **liver disease.**
- you are taking medicines containing buprenorphine, including buprenorphine/naloxone used for treatment of opioid addiction. The use of these medicines together with Nortriptyline Capsules can lead to serotonin syndrome, a potentially life-threatening condition (see “Other medicines and Nortriptyline”).
- You have a cardiac condition called Brugada syndrome

Prolonged QT interval
A heart problem called “prolonged QT interval” (which is shown on your electrocardiogram, ECG) and heart rhythm disorders (rapid or irregular heartbeat) 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 around 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
- in the case of acute surgery, the anaesthetist should be informed about the treatment of Nortriptyline.

Thoughts of suicide and worsening of your depression

This medicine may be associated with thoughts of self-harm and suicidal behaviour in some people.
Tell someone you trust, who can help you in an emergency, that you are taking this medicine and ask that they read this leaflet.
Talk to your trusted person, prescriber or go to a hospital straight away, if after starting this medicine, you have new or worse:
- Feelings of anxiety or irritability
- Feelings of restlessness and agitation
- Extreme increases in activity and difficulty sleeping
- Thoughts of acting on dangerous impulses to harm yourself
- Thoughts about suicide or dying
- Changes in behaviour or mood you, or someone you trust, notices and is worried about

In some people, thoughts of self-harm and suicidal behaviour may be increased when first starting antidepressants. Antidepressants take time to work; and sometimes side effects occur before you or others notice improvements in your mood.
Never stop taking an antidepressant suddenly without first talking to a healthcare professional. Stopping an antidepressant medicine suddenly can cause other symptoms related to withdrawal to occur.
Information from clinical trials has shown the highest risk of thoughts of self harm and suicidal behaviour, is in adults aged less than 25 years who were treated with an antidepressant but the risk applies to people of all ages treated with these medicines.
Call NHS 111 who can offer you support, until you can be with someone who can help you in person.

Sexual Dysfunction
Medicines like Nortriptyline may cause symptoms of sexual dysfunction (see section 4). Rarely people can experience more persistent sexual side-effects after they have stopped taking SSRIs. The term ‘post SSRI sexual dysfunction’ (PSSD) has been used by some people to describe these symptoms. For these people, PSSD can have a significant and distressing impact on their lives. Research is needed to understand why this happens and how common it is. It is important that people experiencing ongoing sexual side-effects receive appropriate and timely support.

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.

Other medicines and Nortriptyline
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, such as:
- 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). These should not be taken at the same time as Nortriptyline Capsules (see section 2 Do not take Nortriptyline if)
- 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
- anticholinergic drugs such as certain medicines to treat Parkinsons disease and gastrointestinal disorders (e.g. atropine, hyoscyamine)
- thioridazine (used to treat schizophrenia)
- tramadol (painkiller)
- medicines to treat fungal infections (e.g. fluconazole, terbinafine, ketoconazole, and itraconazole)
- levothyroxine
- 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)
- ritonavir (used to treat HIV)
- oral contraceptives
- rifampicin (used to treat infections)
- phenytoin and carbamazepine (used to treat epilepsy)
- St. John´s Wort (hypericum perforatum) – a herbal remedy used for depression
- thyroid medication or medication for prostate trouble
- naloxone used for treatment of opioid addiction. These medicines 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
- 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 hayfever)
- 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.

Nortriptyline with alcohol
You should not drink alcohol during treatment with Nortriptyline Capsules 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 for advice before taking this medicine.
Nortriptyline is not recommended 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 breast-feeding for your child and the benefit of therapy for you.

Driving and using machines
Do not drive or work with tools or machinery while 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 contains lactose
If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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.
Not all dosage schemes can be achieved with all the pharmaceutical forms/strengths. The appropriate form/strength should be selected for the starting doses and any subsequent dose increases.

Adults
- The recommended 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, 2-3 times daily for example and be increased gradually as required. Depending on your response to the medicine, your doctor may gradually increase the dose to 150 mg in the evening.
- If your doctor tells you to take more than four 25mg capsules a day, he or she may arrange for you to have regular blood tests.

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. If you require a dose of 50mg or over, your doctor will arrange for you to have a recording of your heart (ECG) and blood tests.

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 should not be used in children and adolescents aged less than 18 years, as safety and efficacy have not been established.

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

Duration of treatment
It may take a few weeks before you feel any improvement. Following remission maintenance treatment may be needed longer term, usually up to 6 months. This should be at the lowest dose that stops the symptoms of depression coming back.

If you take more Nortriptyline than you should
Do not take more capsules than your doctor tells you to. If you ever take too many, or if a child has taken any Nortriptyline, go to the nearest hospital casualty department or tell your doctor at once.
Symptoms of overdose include blurred vision, fast or irregular heartbeats, difficulties passing water, dry mouth and tongue, intestinal blockage, fits, fever, agitation, confusion, hallucinations, uncontrolled movements, low blood

420 mm
210 mm
35 mm
280 mm

pressure, weak pulse, pallor, difficulty breathing, blue discolouration of the skin, decreased heart rate, drowsiness, loss of consciousness, coma, various cardiac symptoms such as heart block, heart failure, cardiogenic shock, metabolic acidosis, hypokalaemia.
An overdose can be very dangerous.

If you forget to take Nortriptyline
If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose do not take a double dose to make up for a forgotten dose, just carry on as before. If you have missed several doses, discuss this with your doctor.

If you stop taking Nortriptyline
Antidepressants may not make you feel better for the first two weeks or more of treatment, so keep taking Nortriptyline Capsules until your doctor tells you to stop. Do not stop these capsules without discussing it with your doctor first.
If you stop using Nortriptyline Capsules abruptly after prolonged therapy you may have withdrawal symptoms, including not being able to sleep, headache, nausea, irritability and sweating.

4. 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:
- 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 a sign of acute glaucoma. (Very rare side effect, may affect up to 1 in 10,000 people).
- Bad constipation, a swollen stomach, fever and vomiting. These symptoms may be due to parts of the intestine becoming paralysed.

(Rare side effect, may affect up to 1 in 1,000 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
- tremor/shakiness 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
- blocked 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 uncontrolled shaking of the body)
- tinnitus (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 outflow 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. cholestatic 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 clumsiness can also occasionally occur
- swelling of the salivary glands
- increases in libido 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
- disorder of the peripheral nerves
- allergic inflammation of the lung alveoli and of the lung tissue
- alterations 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
- paranoia
- dry eyes
- movement disorders (involuntary movements or decreased movements)
- hypersensitivity inflammation of heart muscle
- hepatitis
- hot flush
- syndrome of inappropriate secretion of antidiuretic hormone (SIADH)
- Brugada Syndrome (unmasking) (symptoms may include very fast heartbeat, dizziness, fainting, seizures). Tell your doctor straight away if you get these symptoms.
- Low sodium concentration in the blood
- Not eating (anorexia)

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

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 at 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

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 Nortriptyline contains
- The active substance is Nortriptyline hydrochloride. Each capsule contains 10 mg or 25 mg Nortriptyline hydrochloride.
- 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 Nortriptyline 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.

Nortriptyline 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
Kent Pharmaceuticals Limited, 2nd Floor, Connect 38, 1 Dover Place, Ashford, Kent, England, TN23 1FB.

Manufacturer responsible for batch release
Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

PL 08215/0109
PL 08215/0110

This leaflet was last revised in October 2026

CP.NOR.JNT.C.AP.V8P1