

PACKAGE LEAFLET: INFORMATION FOR THE USER

Nortriptyline 10 mg and 25 mg Film Coated Tablets

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

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, please 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
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

The name of your medicine is Nortriptyline 10 mg or 25 mg Film Coated Tablets. The tablets contain a medicine called nortriptyline hydrochloride. Nortriptyline tablets belong to a group of medicines called tricyclic antidepressants to treat major depression in adults.

2. What you need to know before you take Nortriptyline

Do not take Nortriptyline if you

- are **allergic (hypersensitive)** to Nortriptyline or any other ingredients in this medicine (see section 6)
- have suffered any degree of **heart block, irregular heartbeat or have recently suffered a heart attack**
- suffer from **severe liver disease**
- suffer from a psychological condition known as **mania** (abnormally raised mood)
- are **breast-feeding**
- are taking, or have taken in the last two weeks, a type of anti-depressant described as a **monoamine oxidase inhibitor (MAOI)**
- are taking **adrenaline-like drugs** such as ephedrine, isoprenaline, noradrenaline, phenylephrine, or phenylpropanolamine. The drugs are often contained in cough and cold remedies.

You should not take Nortriptyline if any of the above applies to you. If you are unsure speak to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Nortriptyline if you:

- suffer from **epilepsy** or if you have had a fit or seizure in the past. Nortriptyline may increase the likelihood of an epileptic fit. If after taking Nortriptyline tablets, you

develop a fit for the first time or get more fits than usual, seek medical advice from your doctor.

- have a **history of a mental illness** known as **mania or manic depression**
- suffer from schizophrenia
- suffer from **heart** problems
- suffer from **diabetes**. Nortriptyline may alter your blood sugar levels. Your doctor may need to alter the dose of your insulin or other medicines that help control diabetes
- suffer from an **enlarged prostate**
- suffer from high pressure in the eyes (**glaucoma**)
- are taking medicine for your thyroid
- have had an **allergic reaction to another tricyclic antidepressant** in the past
- are having **Electroconvulsive Therapy (ECT)**
- are elderly as you are liable to experience agitation, confusion, or low blood pressure
- are feeling hostile
- are having an operation under general anaesthetic; discuss this with your GP. You might need to stop taking nortriptyline tablets several days before the operation. If you GP tells you to carry on taking nortriptyline tablets, make sure the doctors treating you in hospital know that you are on nortriptyline
- are pregnant or may be pregnant
- are breast feeding
- have severe liver disease
- have suffered from urinary retention
- have a cardiac condition called Brugada syndrome

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 can take 2 weeks or longer to work. You may be more likely to think like this if you:

- have previously had thoughts about killing or harming yourself.
- are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in young adults (less than 25 years old) 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, close friend or care-giver 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 applies to you speak to your doctor before taking Nortriptyline.

Children and adolescents

Nortriptyline tablets should not be used in children or adolescents.

Other medicines and Nortriptyline

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 can affect or be affected by treatment with Nortriptyline:

- medicines known as **monoamine oxidase inhibitors (MAOI)** such as phenelzine, tranylcypromine and isocarboxazide

- adrenaline-like medicines such as adrenaline, ephedrine, isoprenaline, noradrenaline, phenylephrine and phenylpropanolamine
- moclobemide; you must stop this at least 24 hours before you take nortriptyline
- levothyroxine
- antifungal medicines such as fluconazole and terbinafine
- antihistamines (astemizole and terfenadine)
- tramadol pain killer
- medicines known as **barbiturates** (used for anxiety or for making you feel sleepy)
- **alcohol** (you should not drink alcohol whilst taking Nortriptyline)
- other **tricyclic antidepressants**
- a drug known as **cimetidine** (used to treat heartburn and ulcers)
- another antidepressant known as **fluoxetine**
- a drug known as **carbamazepine**, used in the treatment of epilepsy and other conditions
- medicines such as **guanethidine, debrisoquine, bethanidine, clonidine and reserpine** (used to treat high blood pressure)
- medicines such as **flecainide, propafenone and encainide** (used in the treatment of some heart disorders)
- any other treatment for depression
- anaesthetics – if surgery is necessary this medicine should not be taken, if possible, for several days before the procedure, or the anaesthetist should be informed if you are still taking Nortriptyline
- medicines that interfere with the way Nortriptyline works e.g. quinidine.

Nortriptyline with alcohol

You should not drink alcohol with this medicine.

Excessive consumption of alcohol may lead to increased suicide attempts or overdose, especially if you have a history of emotional disturbances or thoughts of harming or killing yourself.

Pregnancy and Breast-feeding

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Nortriptyline should not be taken by pregnant women, unless your doctor decides otherwise.

Breast-feeding is not recommended whilst taking Nortriptyline.

Driving and using machines

Nortriptyline may affect alertness. Use caution when driving or operating heavy machinery until you are aware of how this medicine affects you. If you feel Nortriptyline affect your ability to drive or use machines, tell your doctor immediately.

Nortriptyline contains lactose

- Lactose intolerance – if you have an intolerance to some sugars, contact your doctor before taking this medicine.
- Diabetes mellitus – Nortriptyline contains 13mg lactose (10mg tablet) or 33mg lactose (25mg tablet) per dose. This should be taken into account for patients with diabetes mellitus.

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 unsure.
- You should **NOT drink alcohol** with this medicine.
- Swallow the tablet **whole with a drink of water**. You may not notice any improvement in your symptoms for up to 4 weeks after starting treatment.

Your doctor will decide the most appropriate dose for you. The recommended dose is:

Adults:

Dosage should begin at a low level (50mg once daily or 25mg 2-3 times daily). If necessary, dose could be gradually increased in 25mg increments no more than rapidly than every other day to be added to the morning dose. The maximum dose is 150 mg per day.

The elderly:

10mg tablet three times a day to start. Dose increases should be gradual by no more than 10mg every other day. If required a dose of 50mg or over the doctor will arrange to have a recording of the heart (ecg) and blood tests.

Lower dosages are recommended for outpatients than for patients in hospital who will be under close supervision. Following effective treatment, a lower dose may be needed longer term. This should be at the lowest dose that stops the symptoms of depression coming back.

The maximum period of treatment should be no more than three months. Another course of treatment should not be started until a full physical examination, including an ECG, has been made.

If you take more Nortriptyline than you should

If you or someone else takes too much Nortriptyline, contact your doctor or nearest hospital emergency department immediately. Take the box and any tablets that are left over with you, if you can.

The symptoms of an overdose may begin within several hours, and include blurred vision, confusion, restlessness and agitation, dizziness, feelings of extreme hot or cold, vomiting, seizures, low blood pressure, coma, problems with the heart, lung, kidneys and liver, and possibly death.

The doctor will assess your condition and decide how to treat an overdose.

If you forget to take Nortriptyline

If you miss a dose, take it as soon as you remember and carry on as before. If it is almost time for your next dose, skip the missed dose and continue as usual. If you have missed several doses, tell your doctor. Do not take a double dose to make up for a missed dose.

If you stop taking Nortriptyline

Do not stop taking the tablets or reduce the dose without telling your doctor first.

If you stop taking the tablets suddenly you may have difficulty sleeping (insomnia), become irritable, and sweat excessively.

If you have further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking Nortriptyline and tell your doctor straight away if you notice any of the following serious side effects:

- if you have thoughts of harming or killing yourself at any time (see section 2).
- if you get a rash or allergic reaction such as itching, swollen lips/tongue or wheezing/shortness of breath.

If you have any of the above side effects, you should tell your doctor immediately.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed;

Heart:

- low or high blood pressure (hypotension or hypertension)
- fast or irregular heart beat
- heart attack (myocardial infarction)
- heart block (symptoms include shortness of breath and fainting)
- stroke
- Brugada Syndrome (unmasking) (symptoms may include very fast heartbeat, dizziness, fainting, seizures). Tell your doctor straight away if you get these symptoms.

Brain and central nervous system:

- confusion (especially in the elderly) with hearing or seeing things (hallucinations)
- not knowing where you are (disorientation)
- false beliefs (delusions)
- anxiety, restlessness, agitation or panic
- difficulty sleeping (insomnia)
- nightmares
- extreme excitement, great optimism and overactivity (hypomania)
- long-lasting abnormal mood
- suicidal thoughts
- numbness, tingling or pins and needles (paraesthesia)
- coordination problems
- abnormal movements or difficulty moving
- nerve damage
- tremors (shaking)
- fits or seizures
- altered brainwave (EEG) patterns
- ringing in the ears (tinnitus)
- dry mouth
- inflamed glands under the tongue or inflamed gums (rarely)
- blurred vision, difficulty focusing or dilated pupils
- constipation, blockage of the digestive tract
- unable to urinate or delayed urination.

Skin:

- rash or small red spots on skin
- itching
- sensitivity to sunlight
- general swelling or swelling of the face and tongue (oedema)
- fever
- reaction to other similar drugs.

Blood:

- blood disorders which may cause you to bruise easily, become anaemic or be unable to fight off infections.

Stomach and intestines:

- feeling (nausea) or being sick (vomiting)
- not eating (anorexia)
- indigestion
- diarrhoea
- changes in taste, inflammation of the mouth
- abdominal cramps
- black tongue
- constipation or blockage of the digestive tract.

Hormones:

- development of breasts in men, breast enlargement and milk production in women
- increased or decreased sex drive
- failure to get an erection (impotence)
- swollen testicles
- changes to blood sugar levels
- altered secretion of antidiuretic hormone (symptoms may include confusion, tremor or seizures).

Other:

- yellow eyes and skin (jaundice)
- liver and kidney problems
- weight gain or loss
- sweating
- flushing or blushing
- passing water often and at night
- sleepiness
- dizziness
- weakness or tiredness
- headache
- swollen glands
- hair loss (alopecia)
- increased risk of bone fractures in patients over 50
- low sodium concentration in the blood.

If you get any side effects, talk to your doctor. This may include any possible side effects not listed in the leaflet. You can also report side effects directly via 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 the label. The expiry date refers to the last day of that month.
- Store in the original container in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of 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 hydrochloride.

Each 10mg tablet contains nortriptyline hydrochloride equivalent to 10mg nortriptyline.

Each 25mg tablet contains nortriptyline hydrochloride equivalent to 25mg nortriptyline.

The other ingredients are; lactose monohydrate, maize starch, dibasic calcium phosphate, polysorbate 80, magnesium stearate (E470b), opadry II 85G58977 White (which contains polyvinyl alcohol-partially hydrolysed, titanium dioxide (E171), talc (E553B), macrogol and lecithin (E322)).

What nortriptyline tablets look like and the contents of the pack

Nortriptyline 25 mg Tablet is a round, white, film coated tablet having a breakline on one face. The breakline is to facilitate the intake and is not intended to divide the tablet in two equal doses. In blister packs of 25 or 100 tablets.

Nortriptyline 10 mg Tablet is a round, white, film coated tablet. In blister packs of 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Blackrock Pharmaceuticals Ltd, The Old Barrel Store, Brewery Courtyard, Draymans Lane, Marlow, SL7 2FF, United Kingdom

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MA Number (25 mg): PLGB 33271/0022

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