

## Package leaflet: Information for the patient

**Nortriptyline 10 mg film-coated Tablets**

**Nortriptyline 25 mg film-coated Tablets**

**Nortriptyline 50 mg film-coated Tablets**

nortriptyline 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, pharmacist or nurse.
- 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 or if you notice any side effects not listed in this leaflet talk to your doctor, pharmacist or nurse. This includes any 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
2. What you need to know before you take Nortriptyline tablets
3. How to take Nortriptyline tablets
4. Possible side-effects
5. How to store Nortriptyline tablets
6. Contents of the pack and other information

### 1. What Nortriptyline tablets are and what they are used for

Nortriptyline tablets contain the active ingredient nortriptyline hydrochloride, which is a tricyclic antidepressant. Nortriptyline tablets relieves symptoms of depression in adults.

### 2. What you need to know before you take Nortriptyline tablets

#### Do not take Nortriptyline 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** or **heartbeat disorder**;
- if you have **severe liver disease**;
- if you suffer from **mania** (abnormally raised mood);
- if you are **breast-feeding**;
- if the **child is under 6 years of age**;
- if you are taking, or have taken in the last two weeks, **monoamine oxidase inhibitors** (another type of antidepressant);
- if you are taking **adrenaline-like drugs** including ephedrine, isoprenaline, noradrenaline, phenylephrine and phenylpropanolamine. These drugs are often contained in cough and cold remedies.

#### Warnings and Precautions

Talk to your doctor or pharmacist before taking Nortriptyline tablets

- if you feel **suicidal** or **aggressive** - tell your doctor;
- if you are **agitated, overactive**, or suffer from **schizophrenia**;
- if you have **heart disease**;
- if you have a cardiac condition called Brugada syndrome
- 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**;
- if you are going to have **electroconvulsive therapy** (electric shock);
- if you are **diabetic**;
- if you are going to receive an **anaesthetic**, e.g. for an operation – tell your doctor;
- if you have had **an allergic reaction to another tricyclic antidepressant** in the past;
- if 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.

The use of Buprenorphine together with Nortriptyline tablets can lead to serotonin syndrome, a potentially life-threatening condition (see “Other medicines and Nortriptyline tablets”).

### **Children:**

Nortriptyline should not be used in the treatment of depression in children and adolescents under the age of 18 years.

### **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 applies to you, tell your doctor or pharmacist.

### **Other medicines and Nortriptyline tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The following medicines may interact with your Nortriptyline tablets:

- **guanethidine, debrisoquine, bethanidine, clonidine** (used to treat high blood pressure);
- **barbiturates** (used for anxiety or to make you feel sleepy);
- **alcohol** (you should not drink alcohol);
- **fluoxetine** (another antidepressant);
- **cimetidine** (for heartburn and ulcers);
- **phenothiazines** (for mental illness);
- **carbamazepine** (for epilepsy);
- **propafenone, flecainide, encainide, quinidine** (for heartbeat disorders);
- **valproic acid** (medicine used for the treatment of epilepsy and bipolar disorder).
- **buprenorphine/opioids:** These medicines 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.

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.

### **Pregnancy and breast-feeding**

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

Do not take Nortriptyline tablets if you are breast-feeding.

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

### **Driving and using machines**

Nortriptyline tablets 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 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 Nortriptyline tablets exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### **Dosage**

#### **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, 3-4 times daily, for example and be increased gradually as required. The maximum dose is 150mg per day.

#### **The elderly:**

The recommended dose is 30 to 50mg/day in divided doses.

Treatment may start with 10mg three times a day. 50 mg tablets are not appropriate for use in elderly patients.

#### **Adolescent patients:**

The recommended dose is 30 to 50mg/day in divided doses.

Treatment may start with 10mg three times a day. 50 mg tablets are not appropriate for use in adolescent patients.

Lower dosages are recommended for outpatients than for patients in hospital who will be under close supervision. Following remission maintenance treatment may be needed longer term.

This should be at the lowest dose that stops the symptoms of depression coming back.

### **Use in Children and adolescents (under age 18)**

Nortriptyline should not be used in the treatment of depression in children and adolescents under the age of 18 years

### **If you take more Nortriptyline tablets than you should**

Go to the nearest casualty department or contact your doctor immediately.

Take the tablet carton with you.

### **If you forget to take Nortriptyline 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 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.**

**Tell your doctor or pharmacist immediately if you experience any of the following serious side effects:**

- sudden chest pain which may spread to the neck or arm, with a shortness of breath and a clammy feeling (these may be signs of a heart attack)
- sudden collapse, numbness or weakness in the arms or legs, headache, dizziness and confusion, disturbances in vision, difficulty swallowing, slurred, mixed up or loss of speech (these may be signs of a stroke)
- inflammation of the liver, yellowing of your skin or whites of your eyes, dark urine, pale stools, tiredness, fever, nausea, weakness, drowsiness and abdominal pain, with test results showing abnormal liver function
- thoughts of harming or killing yourself at any time (see section 2).
- persistent constipation with a swollen stomach, fever and vomiting. These symptoms may be due to parts of the intestine becoming paralysed.
- 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).
- Brugada Syndrome (unmasking) (symptoms may include very fast heartbeat, dizziness, fainting, seizures). Tell your doctor straight away if you get these symptoms.

The following side effects have been reported (Not known: frequency cannot be estimated from the available data):

- low or high blood pressure
- fast or irregular heartbeat
- palpitations
- oedema (swelling of the ankles)
- confusion (especially in the elderly) with seeing or hearing things (hallucinations)
- not knowing where you are (disorientation)
- false beliefs (delusions)
- anxiety, restlessness, agitation
- not sleeping (insomnia)
- nightmares
- panic
- long-lasting abnormal mood
- worsening of mental illness
- numbness, tingling, pins and needles in the hands or feet
- coordination problems
- tremors
- abnormal movements
- fits (seizures)
- altered brainwave (EEG) patterns
- ringing in the ears (tinnitus)
- dry mouth
- rarely, inflamed glands under the tongue or inflammation of the gums (gingivitis)
- blurred vision, difficulty in focusing, dilated pupils
- unable to urinate or delayed urination

- rash
- itching
- light sensitivity
- swelling (oedema)
- fever
- reaction to other similar drugs
- feeling sick (nausea) and vomiting
- not eating (anorexia)
- indigestion
- diarrhoea
- constipation.
- peculiar taste
- inflamed mouth
- abdominal cramps
- black tongue
- development of breasts in men, breast enlargement and milk production in women
- increased or decreased sex drive
- failure to have an erection (impotence)
- swollen testicles
- altered blood sugar levels
- weight gain or loss
- sweating
- flushing
- urinating often and at night
- sleepiness
- dizziness
- weakness
- tiredness
- headache
- swollen glands
- hair loss (alopecia).
- An increased risk of bone fractures has been observed in patients taking this type of medicine.
- Low sodium concentration in the blood

### **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 (see details). By reporting side effects you can help provide more information on the safety of this medicine.

### **United Kingdom**

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

### **5. How to store Nortriptyline 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, label or carton after EXP. The expiry date refers to the last day of that month.

#### *HDPE containers:*

This medicinal product does not require any special storage conditions.

After first opening use within 5 months.

### *Blisters:*

This medicinal product does not require any special storage conditions.

### **Storing your medicine**

Do not use this medicine if you notice any signs of deterioration (for instance change in color)

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 ingredient is nortriptyline hydrochloride.  
Each film-coated tablet contains nortriptyline hydrochloride equivalent to 10 mg, 25 mg, 50 mg nortriptyline base.
- The other ingredients are lactose monohydrate, maize starch, calcium hydrogen phosphate anhydrous, magnesium stearate.
- *Coating:*
- Opadry II Clear:
- Polyvinyl alcohol E 1203
- Polyethyleneglycol / macrogol
- Talc.

### **What Nortriptyline tablets looks like and contents of the pack**

The 10mg tablets are white, round, biconvex film-coated tablets, marked “N10”, 5.5 mm in diameter.

The 25mg tablets are white, round, biconvex film-coated tablets, marked “N25”, 8.0 mm in diameter.

The 50mg tablets are white, round, biconvex film-coated tablets, marked “N50”, 10.2 mm in diameter.

Nortriptyline tablets are available in:

- HDPE bottles with an LDPE, HDPE-lined screw cap with silica gel in pack sizes of 100 tablets.
- PVC/PVDC Blisters lidded with aluminium foil available in pack sizes of 30 tablets

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Focus Pharmaceuticals Limited  
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### **Manufacturer**

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