PATIENT INFORMATION LEAFLET

Nortriptyline 10mg Film-coated tablets
Nortriptyline 25mg Film-coated tablets

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 symptoms 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

This medicine contains nortriptyline.
Nortriptyline Tablets are used in the treatment of symptoms of depression in adults.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NORTRIPTYLINE TABLETS:

Do not take Nortriptyline if:
- you are allergic (hypersensitive) to Nortriptyline or any of the other ingredients of Nortriptyline Tablets (see list of ingredients 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 have severe liver disease;
- you suffer from mania (abnormally raised mood);
- you are breast-feeding;
- the child is under 12 years of age;
- you are taking, or have taken in the last two weeks, monoamine oxidase inhibitors (another type of antidepressant);
- you are taking adrenaline-like drugs including ephedrine, isopren- aline, noradrenaline, phenylephrine and phenylpropanolamine. These drugs are often contained in cough and cold remedies.

Warnings and precautions
Talk to your doctor before taking these tablets if:
- you have a cardiac condition called Brugada syndrome
- you feel suicidal or aggressive – tell your doctor;
- you are agitated, overactive, or suffer from schizophrenia;
- you have heart disease;
- you have a thyroid condition;
- 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;
- you are going to receive an anaesthetic, e.g. for an operation – tell your doctor;
- 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.

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 these points 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.

Other medicines and Nortriptyline 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 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)

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.

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 are lactose intolerant, contact your doctor before taking this medicine.

Nortriptyline 25mg Tablets contain sunset yellow (E110), which may cause allergic reactions.

3. HOW TO TAKE NORTRIPTYLINE TABLETS

Always take Nortriptyline Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Dosage
Adults:
The usual 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.

Elderly:
The usual dose is 30 to 50mg/day in divided doses. Treatment may start with 10mg three times a day.

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

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.

The following side effects have been reported:

- low or high blood pressure
- fast or irregular heartbeat
- palpitations
- heart attack (myocardial infarction)
- stroke
- 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
- co-ordination problems
- tremors
- abnormal movements
- fits (seizures)
- altered brainwave (ECG) 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
- constipation, blockage of the digestive tract
- unable to urinate or delayed urination
- rash
- itching
- light sensitivity
- swelling (oedema)
- fever
- reaction to other similar drugs
- blood disorders which may cause you to bruise easily, become anaemic or be unable to fight off infections
- 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
- yellow eyes and skin (jaundice)
- altered liver function
- inflamed liver (hepatitis) and liver damage
- weight gain or loss
- sweating
- flushing
- urinating often and at night
- sleepiness
- dizziness
- weakness
- tiredness
- headache
- swollen glands
- hair loss (alopecia)

Frequency unknown:

- 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.

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 national reporting system via the Yellow Card Scheme at: www.mhra.gov-.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE NORTRIPTYLINE TABLETS

- Keep 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.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer needed. These measures will help to protect the environment.

6. CONTENTS OF PACK AND OTHER INFORMATION

What Nortriptyline Tablets contain:

The **active** substance is nortriptyline hydrochloride. Each tablet contains the equivalent to 10mg or 25mg of nortriptyline base.

The **other** ingredients are:

Nortriptyline 10 mg

Lactose Monohydrate, Anhydrous Calcium Hydrogen Phosphate, Maize Starch, Magnesium Stearate, Hypromellose (HPMC E-5), Macrogol (PEG 6000).

Nortriptyline 25 mg

Lactose Monohydrate, Anhydrous Calcium Hydrogen Phosphate, Maize Starch, Magnesium Stearate, Hypromellose (HPMC E-5), Macrogol (PEG 6000), Sunset Yellow Lake (E-110) and Titanium dioxide (E-171).

What Nortriptyline Tablets look like and contents of the pack

Nortriptyline 10mg Tablets are white to off coloured, round biconvex, film-coated tablets, debossed with 'N' on one side and 10 on other side.

Nortriptyline 25mg Tablets are orange coloured, round biconvex, film-coated tablets, debossed with 'N25' on one side and scored on other side.

The Tablets are available in PVC/aluminium blister packs of 10s, 30s, 100s.

The Tablets are available in HDPE container with Polypropylene screw on cap pack size: 100 tablets. Discard 60 days after first opening the container

Not all pack sizes may be marketed.

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Marketing Authorisation Holder:
RUDIPHARM LIMITED
Unit 6, Salbrook Road Industrial Estate
Salbrook Road, Redhill, Surrey, RH1 5GJ, UK

Manufacturer:
RUDIPHARM LIMITED
Oak House, Reeds Crescent
Watford, WD24 4QP, UK

To listen to or request a copy of this leaflet in Braille, large print or audio please call, 01293 827819 (UK only)

Please be ready to give the following information:

Product name	Reference number
Nortriptyline 10mg Film-coated Tablets	PL 49565/0090
Nortriptyline 25mg Film-coated Tablets	PL 49565/0091

Nortripttyline Tablets - PIL
Dimensions: 180 x 295 mm (Open size)

Nortriptyline Tablets
Font type: Times New Roman
Headings: 13pt (Bold)
Sub-Heading: 9pt (Bold)
Normal Text: 9pt (Regular)

Color Black