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PACKAGE LEAFLET: INFORMATION FOR THE USER

Nortriptyline 10mg Film-coated Tablets
Nortriptyline 25mg Film-coated Tablets

PHARMA
CODE

XXXX
Pharmacode Reading Direction

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.

What is in this leaflet

- What Nortriptyline Film-coated Tablets are and what they are used for
- What you need to know before you take Nortriptyline Film-coated Tablets
- How to take Nortriptyline Film-coated Tablets
- Possible side effects
- How to store Nortriptyline Film-coated Tablets
- Contents of the pack and other information

1. WHAT NORTRIPTYLINE FILM-COATED TABLETS ARE AND WHAT THEY ARE USED FOR

This medicine contains nortriptyline hydrochloride. Nortriptyline Film-coated Tablets are used in the treatment of symptoms of depression. Nortriptyline Film-coated Tablets may also be used for the treatment of bedwetting in children 6 years and older.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NORTRIPTYLINE FILM-COATED TABLETS

Do not take Nortriptyline if:

- you are allergic (hypersensitive) to Nortriptyline or any of the other ingredients of Nortriptyline Film-coated 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 6 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, 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 Film-coated Tablets if:

- you feel suicidal or aggressive;
- 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;
- your child taking Nortriptyline Film-coated Tablets has a change in behaviour;
- 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 anti-depressant in the past;
- you are pregnant, think you might be pregnant or planning to become pregnant or breast-feeding you should not take Nortriptyline Film-coated 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:

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.

Other medicines and Nortriptyline Film-coated Tablets

You should tell your doctor if you are taking or have taken any medicines, including medicines obtained without a prescription.

The following medicines may interact with your Nortriptyline Film-coated 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 Film-coated Tablets. Your doctor will be able to decide what is suitable for you.

Nortriptyline Film-coated Tablets with food, drink and alcohol

You should not drink alcohol while you are being treated with Nortriptyline Film-coated Tablets. You may find that you get more drunk or feel more depressed.

Pregnancy, breastfeeding and fertility

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.

Driving and using machines

Nortriptyline Film-coated 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 Film-coated Tablets affect your ability to drive or use machines, tell your doctor immediately.

Nortriptyline Film-coated Tablets contains 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 FILM-COATED TABLETS

Always take Nortriptyline Film-coated Tablets 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 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 usual dose is 30 to 50mg/day in divided doses. Treatment may start with 10mg three times a day.

Use in children and adolescents:

The usual dose is 30 to 50mg/day in divided doses. Treatment may start with 10mg three times a day. 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. Children (for bed-wetting only).

Age (years)	Weight		Dose (mg)
	kg	lb	
6-7	20-25	44-55	10
8-11	25-35	55-77	10-20
Over 11	35-54	77-119	25-35

The dose should be given thirty minutes before bedtime. The maximum length of treatment should be three months. Another course of treatment should not be started until a full physical examination has been made.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Nortriptyline Film-coated Tablets 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:

Very common: may affect more than 1 in 10 people

- fast or irregular heartbeat
- dry mouth
- blurred vision
- constipation
- not eating (anorexia)
- indigestion
- constipation.
- abdominal cramps
- black tongue
- sweating

Common: may affect up to 1 in 10 people

- low blood pressure
- palpitations
- heart attack (myocardial infarction)
- stroke
- tremors
- abnormal movements
- altered brainwave (ECG) patterns
- difficulty in focusing, dilated pupils
- blockage of the digestive tract
- failure to have an erection (impotence)
- flushing
- weakness
- tiredness
- headache

Uncommon: may affect up to 1 in 100 people

- high blood pressure
- anxiety, restlessness, agitation
- not sleeping (insomnia)
- nightmares
- numbness, tingling, pins and needles in the hands or feet
- unable to urinate or delayed urination
- feeling sick (nausea) and vomiting
- diarrhoea
- increased or decreased sex drive
- yellow eyes and skin (jaundice)
- weight gain or loss
- urinating often and at night
- sleepiness
- dizziness

Rare: may affect up to 1 in 1,000 people

- confusion (especially in the elderly) with seeing or hearing things (hallucinations)
- ringing in the ears (tinnitus)
- rarely, inflamed glands under the tongue or inflammation of the gums (gingivitis)
- rash
- itching
- light sensitivity
- fever
- peculiar taste
- inflamed mouth
- altered liver function
- swollen glands
- hair loss (alopecia)
- long-lasting abnormal mood
- worsening of mental illness

Very rare: may affect up to 1 in 10,000 people

- oedema (swelling of the ankles)
- fits (seizures)
- swelling (oedema)
- blood disorders which may cause you to bruise easily, become anaemic or be unable to fight off infections
- development of breasts in men, breast enlargement and milk production in women
- swollen testicles
- altered blood sugar levels
- inflamed liver (hepatitis) and liver damage

Not known: frequency cannot be estimated from the available data

- not knowing where you are (disorientation)
- false beliefs (delusions)
- panic
- co-ordination problems
- reaction to other similar drugs
- an increased risk of bone fractures has been observed in patients taking this type of medicine

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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. 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 Nortriptyline Film-coated Tablets after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Discard 100 days after first opening the container.

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 THE PACK AND OTHER INFORMATION

What Nortriptyline Film-coated Tablets contain:

The active substance is nortriptyline hydrochloride. Each film coated tablet contains 10mg or 25mg of Nortriptyline as Nortriptyline hydrochloride.

The other ingredients are:

Nortriptyline 10mg Film-coated Tablets
Microcrystalline cellulose, lactose monohydrate, maize starch, silica colloidal anhydrous (E551), magnesium stearate (E572), isopropyl alcohol, dichloromethane, Instamoistshield IC-MS-218 (white) which contains hypromellose (E464), diethyl phthalate, ethyl cellulose, talc (E553b) and titanium dioxide (E171).

Nortriptyline 25mg Film-coated Tablets
Microcrystalline cellulose, lactose monohydrate, maize starch, silica colloidal anhydrous (E551), magnesium stearate (E572), isopropyl alcohol, dichloromethane, Instamoistshield A21E21116 (Orange) which contains hypromellose (E464), diethyl phthalate, ethyl cellulose, talc (E553b), titanium dioxide (E171), lake quinoline yellow (E104) and lake erythrosine (E127).

What Nortriptyline Film-coated Tablets looks like and contents of the pack

Nortriptyline 10mg Film-coated Tablets are white to off white circular biconvex film coated tablet debossed with "N 10" on one side and plain on other side.

Nortriptyline 25mg Film-coated Tablets are orange coloured, circular biconvex film coated tablet debossed with "N" & "25" separated by break line on one side and plain on other side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Nortriptyline 10 mg Film-coated Tablets and Nortriptyline 25 mg Film-coated Tablets are available in PVC/aluminium blister packs of 10s, 30s, 100s. Not all pack sizes may be marketed. Nortriptyline 10 mg Film-coated Tablets and Nortriptyline 25 mg Film-coated Tablets are available in HDPE container with white child resistant cap pack size: 100 film-coated tablets.

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