

## Package leaflet: Information for the patient

### Nortriptyline Colonis 25mg/ 5 ml Oral Solution

nortriptyline

**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

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

#### 1. What Nortriptyline Oral Solution is and what it is used for

Nortriptyline Colonis 25mg/ 5ml Oral Solution (referred to as Nortriptyline Oral Solution in this leaflet) contains the active ingredient nortriptyline, which is a tricyclic antidepressant.

**Nortriptyline Oral Solution is used to treat major depression in adults.**

#### 2 What you need to know before you take Nortriptyline Oral Solution

**Do not take Nortriptyline Oral Solution 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 have severe liver disease;
- you suffer from mania (abnormally raised mood);
- you are breast-feeding;
- you are a child under the age of six;
- you are taking, or have stopped taking within 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 Oral Solution and wait for 14 days before you start treatment with a monoamine oxidase inhibitor;
- you are taking adrenaline-like drugs (e.g.: ephedrine, isoprenaline, noradrenaline, phenylephrine and phenylpropanolamine). These drugs are often contained in cough and cold drugs.

## Warnings and precautions

### Talk to your doctor or pharmacist before taking Nortriptyline Oral Solution 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;
- 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 take **buprenorphine** or **buprenorphine combined with naloxone** (used to treat opioid dependence or addiction), as the use of Nortriptyline Oral Solution together with these drugs can lead to serotonin syndrome, a potentially life-threatening condition (see ‘Other medicines and Nortriptyline Oral solution’).

### Prolonged QT interval

A heart problem called "prolonged QT interval" (which is shown on your electrocardiogram, ECG) and heart rhythm disorders (**rapid or irregular heart beat**) 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 round 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.

### Thoughts of suicide and worsening of your depression

If you are depressed 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 a hospital straight away.

**You may find it helpful to tell a relative or close friend** that you are depressed and ask them to read this leaflet. You might ask them to tell you if they think your depression 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.

### **Children and adolescents**

Do not give this medicine to children and adolescents aged below 18 years as safety and efficacy have not been established in this age group.

### **Other medicines and Nortriptyline Oral Solution**

Some medicines may affect the action of other medicines and this can sometimes cause serious side effects.

**Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, such as:**

- valproic acid (medicine used for the treatment of epilepsy and bipolar disorder);
- 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 Oral Solution (see section 2 Do not take Nortriptyline Oral Solution);
- adrenaline, ephedrine, isoprenaline, noradrenaline, phenylephrine and phenylpropanolamine (these may be present in cough or cold medicine, and in some anaesthetics) . These should not be taken at the same time as Nortriptyline Oral Solution (see section 2 Do not take Nortriptyline Oral Solution);
- medicine to treat high blood pressure for example calcium-channel blockers (e.g. diltiazem and verapamil), guanethidine, debrisoquine, bethanidine, clonidine, reserpine and methyl dopa;
- anticholinergic drugs such as certain medicines to treat Parkinson's disease and gastrointestinal disorders (e.g. atropine, hyoscyamine);
- thioridazine (used to treat schizophrenia);
- phenothiazines (for mental illness)
- tramadol (painkiller);
- medicines to treat fungal infections (e.g. fluconazole, terbinafine, ketoconazole and itraconazole);
- sedatives (e.g. barbiturates);
- 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);
- oral contraceptives;
- rifampicin (to treat infections);
- phenytoin and carbamazepine (used to treat epilepsy);
- St. John's Wort (*hypericum perforatum*) a herbal remedy used for depression;
- thyroid medication
- the opioid drug buprenorphine or buprenorphine combined with naloxone. These medicines may interact with Nortriptyline Oral Solution 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.

**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 hay fever);
- 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.

### **Taking Nortriptyline Oral Solution with alcohol**

You should **not** drink alcohol while you are being treated with Nortriptyline Oral Solution as alcohol might increase the sedative effect of nortriptyline.

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

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

Nortriptyline should not be used 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.

Do not take Nortriptyline Oral Solution if you are breast-feeding.

### **Driving and using machines**

Do not drive or use machinery when you are on Nortriptyline Oral Solution 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 Colonis 25mg/5ml Oral Solution contains sodium benzoate and sodium.**

This medicine contains 0.50 mg sodium benzoate in each ml.

This medicine contains less than 1 mmol sodium (23 mg) per 30ml oral solution, that is to say essentially 'sodium-free'.

## **3. How to take Nortriptyline Oral Solution**

Always take this medicine 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 (5ml) 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 (2ml), 3-4 times daily, for example and be increased gradually as required. The maximum dose is 150mg (30ml) per day.
- If your doctor tells you to take more than 100mg (20ml of oral solution) a day, he or she may arrange for you to have regular blood tests.

*The elderly:*

The usual dose is 30 to 50 mg/day (6 to 10 ml/day) in divided doses.

Treatment may start at a low level 10-20 mg daily (2-4 ml daily) and may be increased as required to the maximum dose of 50mg (10ml). If you require a dose of 50mg (10ml) 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. **Do not take** Nortriptyline Oral Solution if you have severe liver disease (see section 2 Do not take Nortriptyline Oral Solution).

*Use in children and adolescent patients:*

Nortriptyline Oral Solution 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.

**Method of administration**

Nortriptyline Oral Solution is for oral use.

A double-ended dosing spoon is provided with the product. The small spoon measures a 2.5 ml dose and the larger spoon measures 5 ml.

Pour the liquid into the dosing spoon according to your dose. Do not overfill the spoon.

After taking your dose you should wash the dosing spoon with water and leave to air dry.

**If you take more Nortriptyline Oral Solution than you should**

Do not take more oral solution than your doctor tells you to. If you ever take too much, 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 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 and hypokalaemia.

**An overdose can be very dangerous.**

### **If you forget to take Nortriptyline Oral Solution**

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 Oral Solution**

Antidepressants may not make you feel better for the first two weeks or more of treatment, so keep taking Nortriptyline Oral Solution until your doctor tells you to stop. Do not stop taking the oral solution or reduce the dose without telling your doctor first.

If you stop using Nortriptyline Oral Solution abruptly after prolonged therapy you may have withdrawal symptoms, including not being able to sleep, headache, nausea, irritability and sweating.

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.

### **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 signs 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 (Not known side effect, cannot be estimated from the available data).

The following side effects have also been reported:

**Very common:** may affect more than 1 in 10 people.

- dry mouth
- excessive sweating
- constipation
- nausea (feeling sick)
- headache
- tremor
- dizziness

- blocked nose
- accommodation disorder of the eyes
- irregular or heavy heart beats
- weight gain
- aggression

**Common:** may affect up to 1 in 10 people.

- fatigue
- dizziness when you stand up due to low blood pressure (orthostatic hypotension)
- disturbed coordination
- disturbed attention
- confusion (especially in the elderly with seeing and hearing things (hallucinations))
- not knowing where you are (disorientation), false beliefs (delusions), panic
- heart block
- a heart problem called "prolonged QT interval" (which is shown on your electrocardiogram, ECG)
- changes in taste
- blurred vision (dilated pupils)
- increased or decreased sex drive
- failure to have an erection (impotence)
- agitation
- tingling in arms & legs
- problems urinating (increased or decreased)
- feeling thirsty
- low sodium concentration in the blood

**Uncommon:** may affect up to 1 in 100 people.

- changes in sleep patterns (including nightmares)
- mania and hypomania (excitement or euphoria)
- vomiting
- high blood pressure
- anxiety
- diarrhoea
- liver problems
- increased production or outflow of breast milk without breast feeding
- increased pressure in the eye ball
- collapse conditions
- worsening of cardiac failure
- convulsions (body muscles contract and relax rapidly and repeatedly, resulting in an uncontrolled shaking of the body)
- ringing sounds in ear
- an enlarged or swollen tongue
- skin rash
- swelling of the face
- unable to empty the bladder (urinary retention)

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

- mouth or gum problems
- delirium, especially in the elderly perhaps with anxiety and restlessness
- hallucinations (in patients with schizophrenia)
- a rash, which may be itchy or get worse in sunlight
- decreased appetite

- hair loss
- enlargement of male breast tissue
- weight loss
- abnormal results of liver function tests
- fever (pyrexia)
- jaundice
- feeling of restlessness (akathisia), involuntary movement (dyskinesia)
- slow or fast heart beat (arrhythmia)
- intestinal obstruction (paralytic ileus)
- bone marrow depression
- decrease in the number of white blood cells (leucopenia and agranulocytosis)
- higher than normal level of certain type of white blood cells (eosinophilia)
- low blood platelet count (thrombocytopenia)
- swelling of the salivary gland (salivary gland enlargement)

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

- increased pressure within eye
- abnormal heart rhythm that can lead to sudden cardiac death (so called torsades de pointes)
- heart muscle disease
- allergic inflammation of the lung alveoli and of the lung tissue

**Not known:** frequency cannot be estimated from the available data

- changes of blood sugar levels
- paranoia
- movement disorders (involuntary movements or decreased movements)
- hypersensitivity inflammation of heart muscle
- hepatitis
- syndrome of inappropriate secretion of antidiuretic hormone (SIADH), when the body retains too much water
- suicidal ideation and suicidal behaviour
- abnormal high body temperature due to failed thermoregulation (hyperthermia)
- blood disorders which may cause you to bruise easily, become anaemic or be unable to fight off infections
- heart attack (myocardial infarction)
- stroke
- numbness, tingling, pins and needles in the hands or feet
- coordination problems
- fits (seizures)
- sleepiness
- blurred vision, difficulty in focusing, dilated pupils
- flushing
- rarely, inflamed glands under the tongue or inflammation of the gums (gingivitis)
- indigestion, abdominal cramps
- inflamed mouth
- black tongue
- unable to urinate or delayed urination
- urinating often and at night
- swollen testicles
- weakness and tiredness

Abrupt cessation of treatment after prolonged therapy may cause nausea, headache and malaise, these are withdrawal symptoms.



There may be an increased risk of bone fractures in patients 50 years and older taking nortriptyline.

### **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 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.

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Nortriptyline Oral Solution**

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 carton and label after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

### **After first opening use within 3 months.**

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 Oral Solution contains**

- The active substance is nortriptyline. Each 5 ml of Nortriptyline Oral Solution contains 25mg of nortriptyline (as nortriptyline hydrochloride).
- The other ingredients are: sodium benzoate (E211), sucralose, purified water and hydrochloric acid (for pH adjustment).

### **What Nortriptyline Oral Solution looks like and contents of the pack**

Nortriptyline Oral Solution is a clear colourless and odourless solution. It is supplied in a 250 ml, amber, type III glass bottle, safely closed with a child-resistant, screw cap with tamper evident closure.

A double-ended dosing spoon is also provided to measure doses as prescribed by the doctor.

### **Marketing Authorisation Holder**

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