

NORTRIPTYLINE TABLETS

Nortriptyline hydrochloride (10mg, 25mg)

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What *Nortriptyline* Tablets is used for

Nortriptyline relieves the symptoms of depression. *Nortriptyline* may also be used for the treatment of bed-wetting in children 6 years and older.

Your doctor may have prescribed *Nortriptyline* for another reason. Ask your doctor if you have any questions about why *Nortriptyline* has been prescribed for you.

How *Nortriptyline* Tablets works

Nortriptyline Tablets contain the active ingredient nortriptyline hydrochloride. *Nortriptyline* belongs to a group of medicines called tricyclic antidepressants (TCAs). TCAs are thought to work by their action on brain chemicals involved in controlling mood.

Before you use *Nortriptyline* Tablets

- When you must not use it

Do not take *Nortriptyline* if

- you are allergic (hypersensitive) to *nortriptyline* or any of the other ingredients of *Nortriptyline* tablets (see section **Product Description**). 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 (MAOIs; another type of

antidepressant).

- Before you start to use it

Please discuss with your doctor or pharmacist before taking *Nortriptyline*

Tell your doctor if you:

- suffer from other mental illnesses
- have a heart, kidney or liver problem
- have seizures or fits
- have diabetes
- have thyroid disease
- have raised pressure in your eye (glaucoma)
- have difficulty passing urine
- are going to undergo surgery

Tell your doctor if you are pregnant, think you might be pregnant now, are planning to become pregnant or if you are breast-feeding. Do not take *Nortriptyline* until you and your doctor have discussed the risks and benefits involved.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

The following medicines may interact with your *Nortriptyline*:

- 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);
- cough and cold remedies
- anaesthetics (medicines used in surgery)

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.

Other medicines not listed above may also interact with *Nortriptyline*. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use *Nortriptyline* Tablets

- How much to use

Adults:

In the treatment of depression:

The initial adult dose is 10 mg three

times daily. Since *Nortriptyline* has a prolonged half-life, once daily dosage regimens are also suitable, usually given at night.

Nortriptyline is given by mouth as the hydrochloride in doses equivalent to *Nortriptyline* 20 to 40 mg daily in divided doses increasing to 100 mg daily as necessary. The usual maintenance dose is 30 to 75 mg daily.

Children (for bed-wetting only)

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

- When to use it

Use as directed by your doctor or pharmacist.

The dose should be given thirty minutes before bedtime.

- How long to use it

Continue taking *Nortriptyline* for as long as your doctor recommends.

For the treatment children having problem with bed wetting, 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.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

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 use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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Symptoms of an overdose may include irregular heartbeat and fits.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Nortriptyline* Tablets.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not take any new medicines without consulting your doctor.

Do not give *Nortriptyline Tablets* to anyone else, even if they have the same symptoms or condition as you.

Do not stop taking *Nortriptyline Tablets* or lower the dose without first checking with your doctor. Stopping this medicine suddenly may cause some unwanted effects. Your doctor will explain how you should slowly reduce your dose of *Nortriptyline Tablets* before you can stop taking it completely.

- Things to be careful of

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.

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 apply to you, tell your doctor or pharmacist.

Driving and using machines

Nortriptyline 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.

Combining *Nortriptyline* tablets and alcohol can make you more sleepy, dizzy or lightheaded. Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking this medicine.

Nortriptyline tablets contain lactose. If you are lactose intolerant, contact your doctor before taking this medicine.

Side effects

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

Tell your doctor immediately if you notice any of the following side effects:

- Dry mouth, sedation, blurred vision, constipation, nausea, difficulty with difficulty in urination (due to anticholinergic action).
- Other common side-effects are cardiovascular (postural hypotension, rapid heartbeat, temporary loss of consciousness, particularly with high doses), sweating, tremor, rashes, behavioural disturbances (particularly with children), confusion (particularly in the elderly), interference with sexual function.
- Less commonly black tongue, weakness in the intestinal tract, fits, lack of white blood cells, increase of eosinophil in the blood, rash or purple spots on the skin caused by internal bleeding from blood vessels, platelets deficiency in the blood and yellow of skin and eyes.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and disposal of *Nortriptyline Tablets*

- Storage

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 label and blister foil. The expiry date refers to the last day of that month.

Store below 25°C, protected from light and moisture.

- Disposal

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

Product description

- What it looks like

Nortriptyline 10mg and 25mg are red brownish, round, sugar-coated tablets.

- Ingredients

- Active ingredient:

The active substance is *Nortriptyline hydrochloride*. Each tablet contains 10mg or 25mg *Nortriptyline hydrochloride*.

- Inactive ingredients:

Core: Lactose, Microcrystalline Cellulose, Sodium Starch Glycollate, Maize Starch, Colloidal Silicon Dioxide, Magnesium Stearate, Talc

Sugar coating: Gelatin, Talc, Calcium carbonate, Ponceau 4E E.124, Hypromellose, Titanium Dioxide

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- MAL number(s):

Nortriptyline 10mg: MAL19861450A

Nortriptyline 25mg: MAL19861453A

Manufacturer

Remedica Ltd,
Aharmon Str. Limassol Industrial Estate,
3056 Limassol, Cyprus, EU.

Product Registration Holder

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