

NEW ZEALAND CONSUMER MEDICINE INFORMATION

NORPRESS

Nortriptyline (as hydrochloride) 10mg & 25mg tablets



What is in this leaflet

This leaflet answers some common questions about Norpress. It does not contain all the information available on this medicine.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Norpress against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet. You may want to read it again.

What NORPRESS is used for and how it works

Your Norpress tablets contain the active ingredient nortriptyline hydrochloride. It belongs to a group of medicines known as tricyclic antidepressants (TCAs).

Norpress is used to treat depression. Depression is thought to be caused by a chemical imbalance in parts of the brain. This affects your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, being unable to enjoy life, poor appetite or overeating, disturbed sleep, often waking up early, loss of sex drive, lack of energy and feeling guilty over nothing. Norpress works by correcting this chemical imbalance and may help relieve the symptoms of depression.

Norpress is also used as an aid to smoking cessation and may help you stop smoking.

Your doctor may, however, prescribe Norpress for another reason. Ask your doctor if you have any questions about why Norpress has been prescribed for you.

Norpress is not recommended for use in children 12 years of age and under.

Norpress is not recommended for use in adolescents (13-18 years of age) for the treatment of depression, unless under the supervision of a specialist.

Norpress is not recommended for use in adolescents (under 18 years of age) as an aid in smoking cessation.

Norpress is available on prescription from your doctor.

Before you take NORPRESS

When you must not take it

Do not take Norpress if you:

- **Are allergic to nortriptyline, other tricyclic antidepressants or any other ingredients listed at the end of this leaflet**
- **Are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking a MAOI within the last 14 days.** Ask your doctor or pharmacist if you are unsure as to whether or not you are taking a MAOI
- **Have recently had a heart attack.**

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing;

swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Before you take it

Tell your doctor if you:

- Are allergic to any other medicines, foods, preservatives or dyes
- Are pregnant, plan to become pregnant or are breastfeeding
- Have a heart, kidney or liver problem
- Have epilepsy, fits or convulsions
- Have diabetes
- Have an overactive thyroid gland (hyperthyroidism) or are receiving thyroid medication
- Have raised pressure in your eye (glaucoma)
- Have had a serious head injury or have brain damage
- Have difficulty passing urine
- Suffer from mania (mood of excitement, over-activity and uninhibited behaviour) or bipolar disorder
- Are a heavy drinker
- Take sedatives or stimulants
- Are having electrical shock treatment
- Have suicidal thoughts or have attempted suicide in the past.

If you are pregnant or plan to become pregnant you need to discuss with your doctor the risks and benefits of taking amitriptyline during pregnancy. The general condition of your newborn baby might be affected by the medicine. If your baby has been exposed to this medicine during the last three months of pregnancy it may suffer withdrawal symptoms such as trouble with breathing, fits, feeding difficulties, vomiting, stiff or floppy muscles, vivid reflexes, tremor, jitteriness, irritability, constant crying, and sleepiness. If your

newborn baby has any of these symptoms, please contact your doctor immediately.

If you have not told your doctor about any of the above, or any other medical condition, tell him/her before you start taking Norpress.

Taking other medicines

If you are taking any other medicines, including any you get without a prescription from a pharmacy, supermarket or health food shop, tell your doctor or pharmacist.

Medicines that may interfere with Norpress include:

- Other antidepressant medicines including:
 - monoamine oxidase Inhibitors (MAOI'S) (e.g. phenelzine, tranylcypromine)
 - selective serotonin reuptake inhibitors (SSRI's) (e.g. citalopram, fluoxetine)
 - tricyclic antidepressants (e.g. amitriptyline, imipramine)
- Some medications used to lower blood pressure (e.g. guanethidine)
- Sympathomimetics, such as nasal decongestants (used for colds or hay fever)
- Anticholinergics medicines (e.g. ipratropium, propantheline, oxybutynin)
- Cimetidine (used to treat ulcers and other stomach complaints)
- Medicines used to treat thyroid problems
- Some medications used to treat heart conditions (e.g. propafenone, flecainide)
- Carbamazepine, a medicine used to treat epilepsy.

These medicines may be affected by Norpress or may affect how well Norpress works. You may need different amounts of your medicines or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be

careful with or avoid while taking Norpress.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to take NORPRESS properly

How much to take

Your doctor will tell you how much Norpress you need to take each day. It is important that you take Norpress as directed by your doctor. Do not take more than the recommended dose.

For the Relief of Symptoms of Depression

It may take several weeks before any response to Norpress is noticeable.

The usual dose for an adult is 25mg of nortriptyline 3 or 4 times daily. If necessary, your doctor may increase the dose up to a maximum of 100mg daily.

If you are elderly you may be started on a lower dose of 25 to 50mg per day, in divided doses.

Your doctor may tell you to take different doses to these. If so, follow their instructions.

As an Aid in Smoking Cessation

The recommended starting time is 10 - 28 days prior to the quit date.

The usual starting dose is 25mg per day. This dose will usually be increased over a period of ten days to five weeks, to achieve a maintenance dose of 75 to 100mg per day.

Your doctor may tell you to take different doses to these. If so, follow their instructions.

Norpress and nicotine patches should only be used together under the supervision of your doctor.

How to take it

Swallow the tablets with a glass of water or other liquid. Do not crush or chew the tablets.

Norpress 25mg tablets can be broken in half if your doctor has prescribed half a tablet. Do not halve the 10 mg tablet.

Norpress tablets can be taken with or without food.

How long to take it

For depression, the length of treatment will depend on how quickly your symptoms improve. Most antidepressants including Norpress take time to work so don't feel discouraged if you do not feel better right away. Keep taking the tablets every day. Do not stop taking Norpress even if you begin to feel better, unless your doctor tells you to do so. Make sure you do not run out of tablets.

For smoking cessation, the usual length of treatment is 12 weeks. However, your doctor may tell you take Norpress for up to 6 months. Continue taking Norpress until your doctor tells you to stop.

If you forget a dose

If you forget a dose, skip the dose you missed and take the next dose when you are meant to. Do not try to make up for the dose you missed by taking more than one dose at a time.

Taking your medicine at the same time each day may help you to remember to take it regularly. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking NORPRESS

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking Norpress.

Tell your doctor or pharmacist that you are taking Norpress before you start any new medicines.

Tell your doctor if you develop a skin rash or hives while taking Norpress.

Tell your doctor if you become pregnant while taking Norpress.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Norpress.

If you are going to have any blood tests, tell your doctor that you are taking Norpress.

Keep all appointments you and your doctor have scheduled so that your progress can be followed.

Tell your doctor if you notice any of the following, especially if they are severe, happen suddenly, or if you had not had these symptoms before: anxiety or agitation, panic attacks, difficulty sleeping, irritability, aggressiveness, impulsivity, restlessness, over-activity or uninhibited behaviour or worsening of depression.

Tell your doctor immediately if you have any distressing thoughts (thought of suicide or self-harm) or experiences during this initial period or at any other time.

Things you must not do

Do not take Norpress to treat any other complaints unless your doctor tells you to.

Do not stop taking Norpress or lower the dose without first checking with your doctor. Suddenly stopping Norpress may cause unwanted side effects.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

Norpress may cause drowsiness in some people. Be careful when driving, operating machinery or performing jobs that need you to be alert, until you are certain that Norpress does not affect your performance.

Be careful when drinking alcohol while taking Norpress. Combining

Norpress and alcohol can make you more sleepy, dizzy or lightheaded. Your doctor may suggest avoiding alcohol while you are taking Norpress.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking Norpress.

All medicines can have some unwanted effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Stomach or bowel problems (e.g. nausea, diarrhoea, constipation)
- Dry mouth or taste change
- Change in appetite
- Shakiness or tremor
- Trouble sleeping
- Dizziness or light-headedness (especially on standing rapidly)
- Tingling or numbness of the hands or feet
- Ringing or other persistent noise in the ears
- Difficulty in passing urine.

These are the more common side effects of Norpress.

Tell your doctor as soon as possible if you notice any of the following:

- Changes in the speed of your heart rate (increase or decrease) or irregular heart beat
- Agitation, anxiety, worsening of depression
- Confusion or hallucinations (seeing or hearing things that are not there)
- Vision problems
- Yellowing of the eyes or skin (jaundice).

These side effects may be serious. You may need urgent medical attention. These side effects are rare.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- Symptoms of an allergic reaction (symptoms include: swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing)
- Severe chest pain or tightness
- Thoughts of suicide
- Fainting, seizures or fits.

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

The list of side effects mentioned above is not complete. Others side effect may occur in some people and there may be some side effects not yet known.

See your doctor if you experience any of the following when you stop Norpress treatment:

- Nausea
- Headache
- Malaise (a general feeling of being unwell).

These symptoms are generally not serious and disappear within a few days.

The list of side effects mentioned above is not complete. If you should suffer from any of these side effects or any other undesired effect tell your doctor or pharmacist.

If you should suffer from any of these side effects or any other undesired effect tell your doctor or pharmacist.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

In case of overdose

You should only take the number of tablets that you have been told.

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the

Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any Norpress by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the pack of Norpress with you if you can.

Keep telephone numbers for these places handy.

Storage conditions

Do not take this medicine after the expiry date shown on the pack/blister strip or if the packaging shows signs of tampering.

Keep your Norpress tablets in the blister pack until it is time to take them.

Store below 25°C and out of reach of children. Avoid exposure to heat, light and moisture.

Do not store Norpress, or any other medicine, in the bathroom or near a sink.

Disposal

If your doctor tells you to stop taking Norpress or if the tablets have passed the expiry date, ask your pharmacist what to do with the remaining medicine.

Product Description

What Norpress tablets look like

Norpress 10mg tablets are yellow, film coated convex tablets, 5.6mm in diameter, and blank on both sides.

Norpress 25mg tablets are orange, film coated convex tablets, 8.7mm in diameter, with a scoreline on one side and blank on the other.

Ingredients

Each Norpress 10mg tablet contains the active ingredient Nortriptyline (as the hydrochloride), equivalent to 10mg nortriptyline.

Each Norpress 25mg tablet contains the active ingredient Nortriptyline (as the hydrochloride), equivalent to 25mg nortriptyline.

The 10mg tablets also contain the following ingredients Lactose, Maize starch, Magnesium stearate, Polyvinyl alcohol, Talc, Titanium dioxide, Macrogel/PEG 3350, Lecithin, Quinoline yellow and Iron oxide yellow.

The 25mg tablets also contain the following ingredients Lactose, Maize starch, Magnesium stearate, Polyvinyl alcohol, Talc, Titanium dioxide, Macrogel/PEG 3350, Lecithin, Sunset yellow FCF, Brilliant blue FCF and Allura Red AC.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11-183,
Eilerslie,
Auckland.

Phone: (09) 579 2792

Date of information

23 July 2010

(Based on Norpress datasheet 23 June 2010)