

NORTRIPTIMED

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using NORTRIPTIMED?

NORTRIPTIMED contains the active ingredient nortriptyline hydrochloride. NORTRIPTIMED is used to treat depression. For more information, see Section [1. Why am I using NORTRIPTIMED?](#) in the full CMI.

2. What should I know before I use NORTRIPTIMED?

Do not use if you have ever had an allergic reaction to nortriptyline or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use NORTRIPTIMED?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with nortriptyline hydrochloride and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use NORTRIPTIMED

- Your doctor will tell you how much NORTRIPTIMED you need to take each day.
- The usual dose for an adult is 25 mg of nortriptyline 3 or 4 times daily. If necessary, your doctor may increase the dose up to a maximum of 100 mg daily. If you are elderly you may be started on a lower dose of 25 to 50 mg per day, in divided doses

More instructions can be found in Section [4. How do I use NORTRIPTIMED?](#) in the full CMI.

5. What should I know while using [medicine name]?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using NORTRIPTIMED.• Watch carefully for signs that your depression or anxiety is getting worse, especially in the first few weeks of treatment.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly without first checking with your doctor.• Do not stop taking NORTRIPTIMED or lower the dose without first checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Do not drive or operate machinery until you know how NORTRIPTIMED affects you.
Drinking alcohol	<ul style="list-style-type: none">• Be careful when drinking alcohol while taking NORTRIPTIMED. Combining NORTRIPTIMED and alcohol can make you more sleepy, dizzy or light-headed.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the blister pack until it is time to take them• Keep your tablets in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using NORTRIPTIMED?](#) in the full CMI.

6. Are there any side effects?

Drowsiness, blurred vision, constipation, diarrhoea and stomach pain, vomiting, dizziness, nausea, dry mouth and difficulty passing urine are common side effects of tricyclic antidepressants.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

NORTRIPTIMED

nortriptyline hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using NORTRIPTIMED. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using NORTRIPTIMED.**

Where to find information in this leaflet:

- [1. Why am I using NORTRIPTIMED?](#)
- [2. What should I know before I use NORTRIPTIMED?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use NORTRIPTIMED?](#)
- [5. What should I know while using NORTRIPTIMED?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using NORTRIPTIMED?

NORTRIPTIMED contains 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. NORTRIPTIMED is belongs to a group of medicines called tricyclic antidepressants (TCAs). TCAs are thought to work by their action on brain chemicals called amines which are involved in controlling mood.

2. What should I know before I use NORTRIPTIMED?

Warnings

Do not use NORTRIPTIMED if:

- 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.

Check with your doctor if you:

- have or have had any medical conditions, especially the following:
 - 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 a 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
 - Take any weight loss medicines
 - Are having electrical shock treatment
 - Have suicidal thoughts or have attempted suicide in the past.

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

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

NORTRIPTIMED is not recommended for use in adolescents (under 18 years of age) as an aid in smoking cessation. During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

NORTRIPTIMED is not recommended to be used during pregnancy. Your doctor will discuss the risks and benefits of using NORTRIPTIMED if you are pregnant.

If you are pregnant or plan to become pregnant you need to discuss with your doctor the risks and benefits of taking NORTRIPTIMED 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 NORTRIPTIMED.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known whether NORTRIPTIMED passes into breast milk.

3. What if I am taking other medicines?

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

Some medicines may interfere with NORTRIPTIMED and affect how it works.

- 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
- Phenothiazines – which includes some antipsychotic and antihistamine medicines.
- Other medicines which may increase serotonin toxicity including amphetamines, tryptophan, fenfluramine, fentanyl analogues, tramadol, 5-HT agonists, dextromethorphan, pethidine and methadone.

These medicines may be affected by NORTRIPTIMED or may affect how well NORTRIPTIMED 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 NORTRIPTIMED. Ask your doctor or pharmacist if you are not sure about this list of medicines.

4. How do I use NORTRIPTIMED?

How much to take

Your doctor will tell you how much NORTRIPTIMED you need to take each day. It is important that you take

NORTRIPTIMED 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 NORTRIPTIMED is noticeable. The usual dose for an adult is 25 mg of nortriptyline 3 or 4 times daily. If necessary, your doctor may increase the dose up to a maximum of 100 mg daily. If you are elderly you may be started on a lower dose of 25 to 50 mg 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 25 mg 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 100 mg per day. Your doctor may tell you to take different doses to these. If so, follow their instructions. NORTRIPTIMED 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. NORTRIPTIMED 25 mg tablets can be broken in half if your doctor has prescribed half a tablet. Do not halve the 10 mg tablet. NORTRIPTIMED tablets can be taken with or without food.

How long do take it

For depression, the length of treatment will depend on how quickly your symptoms improve. Most antidepressants including NORTRIPTIMED 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 NORTRIPTIMED 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 NORTRIPTIMED for up to 6 months. Continue taking NORTRIPTIMED until your doctor tells you to stop.

If you forget to use NORTRIPTIMED

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.

5. What should I know while using NORTRIPTIMED?

Things you should do

- Tell all doctors, dentists and pharmacists who are treating you that you are taking NORTRIPTIMED.
- Tell your doctor or pharmacist that you are taking NORTRIPTIMED before you start any new medicines.
- Tell your doctor if you develop a skin rash or hives while taking NORTRIPTIMED.
- Tell your doctor if you become pregnant while taking NORTRIPTIMED.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking NORTRIPTIMED.
- If you are going to have any blood tests, tell your doctor that you are taking NORTRIPTIMED.
- 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, impulsivity, irritability, aggressiveness, 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 should not do

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

Do not stop taking NORTRIPTIMED or lower the dose without first checking with your doctor. Suddenly stopping NORTRIPTIMED 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

NORTRIPTIMED 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 NORTRIPTIMED does not affect your performance.

Be careful when drinking alcohol while taking NORTRIPTIMED. Combining NORTRIPTIMED and alcohol can make you more sleepy, dizzy or lightheaded. Your doctor may suggest avoiding alcohol while you are taking NORTRIPTIMED.

An increased risk of bone fracture has been observed in patients taking this type of medicine.

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 NORTRIPTIMED by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the pack of NORTRIPTIMED with you if you can.

Keep the telephone numbers for these places handy.

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in cool dry place where the temperature stays below 25°C and away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Stomach or bowel problems (e.g. nausea, diarrhoea, constipation)• Dry mouth or taste change• Change in appetite• Shakiness or tremor• Trouble sleeping• Dizziness or lightheadedness (especially on standing rapidly)• Tingling or numbness of the hands or feet ☐ Ringing or other persistent noise in the ears• Difficulty in passing urine.	Speak to your doctor if you have any of these less serious side effects and they worry you.
<p>These are common side effects of tricyclic antidepressants.</p> <ul style="list-style-type: none">• Changes in the speed of your heart rate (increase or decrease) or irregular heart beat	Tell your doctor as soon as possible if you notice any of the following:

<ul style="list-style-type: none"> • 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. 	
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Serious side effects

Serious side effects	What to do
<p>These side effects are uncommon but may be serious and need urgent medical attention.</p> <ul style="list-style-type: none"> • Symptoms of an allergic reaction (symptoms include: swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing) • symptoms of Serotonin Syndrome such as fever, sweating, confusion, agitation, diarrhoea and muscle spasms. Serotonin Syndrome symptoms vary, are not specific and may result from the interaction of NORTRIPTIMED with other medicines, such as SSRIs (refer to Taking other medicines section), • Severe chest pain or tightness • Thoughts of suicide • Fainting, seizures or fits. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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 NORTRIPTIMED 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.

7. Product details

This medicine is only available with a doctor's prescription.

What NORTRIPTIMED contains

Active ingredient (main ingredient)	10mg or 25mg nortriptyline hydrochloride.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • Pregelatinized maize starch, • magnesium stearate, • lactose monohydrate, • calcium hydrogen phosphate <p>NORTRIPTIMED 10 mg tablets also contains Opadry YS-1-7006 Clear as the coating agent which consist of: HPMC 2910/Hypromellose Macrogol/PEG 8000 Macrogol/PEG 400</p> <p>NORTRIPTIMED 25 mg tablets also contains Opadry 03G230003 Orange as the coating agent which consist of HPMC 2910/Hypromellose Macrogol/PEG 8000 Macrogol/PEG 400 sunset yellow FCF/ Fd&C Yellow #6</p>
Potential allergens	sugars as lactose

Do not take this medicine if you are allergic to any of these ingredients.

What NORTRIPTIMED looks like

NORTRIPTIMED 10 mg tablets are presented as white, round (diameter 5.5 mm), biconvex film coated tablets debossed with "10" on one side.

NORTRIPTIMED 25 mg tablets are presented as orange, round (diameter 8 mm), biconvex film coated tablets with score line and debossed with "25" on the other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Who supplies NORTRIPTIMED

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Marketed and distributed by

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Telephone 1300 788 261
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