

ALLEGRON®

Nortriptyline (as hydrochloride) 10 mg & 25 mg tablets

What is in this leaflet

Please read this leaflet carefully before you start using Allegron

This leaflet answers some common questions about Allegron. It does not contain all the available information. 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 using Allegron against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Allegron is used for

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

Allegron is used to treat depression. Depression may affect your whole body and may 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.

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

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

**Allegron is not recommended for use in children 12 years of age and under.
Allegron is not recommended for use in adolescents (13-18 years of age) for the treatment of depression, unless under the supervision of a specialist.**

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

Allegron is only available on prescription from your doctor.

Before you use Allegron

When you must not use it

Do not use Allegron 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.

If you are not sure whether you should start using Allegron, talk to your doctor.

Before you start to use it

Tell your doctor if:

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start using Allegron.

Tell your doctor if:

- 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
- Take any weight loss medicines

- 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 Allegron 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 Allegron

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Allegron.

Some medicines may interfere with Allegron. These 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
- 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 Allegron, or may affect how well it works. You may need different amounts of your medicine, 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 Allegron.

How to use Allegron

How much to take

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

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

When to take it

ALLEGRON can be taken with or without food. Tablets should be swallowed whole with a glass of water.

How long to take it

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

If you forget to take it

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 using Allegron

Things you must do

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

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Allegron.

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

Tell your doctor if you become pregnant while taking Allegron.

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

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

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 must not do

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

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

Allegron 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 Allegron does not affect your performance.

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

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

In case of overdose

If you take too much (overdose)

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

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Allegron.

Do this even if there are no signs of discomfort or poisoning.

If you have taken too much Allegron you may exhibit the following signs: - confusion, blurred vision, drowsiness, hallucinations, agitation, vomiting, dizziness, body temperature changes (low and high), difficulty in breathing and increased or irregular heartbeat.

Side Effects

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

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

These are the more common side effects of Allegron.

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)
- 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 Allegron with other medicines, such as SSRIs (refer to Taking other medicines section),
- 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 Allegron 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.

After using Allegron

Storage

- Keep your tablets in a cool dry place where the temperature stays below 25°C.
- Keep your tablets in the blister pack until it is time to take them. If you take your tablets out of the blister pack, they may not keep as well.

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

Store it in a cool dry place 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.

There will be an expiry date (month, year) on your ALLEGRON carton. The medicine should not be taken after this date because it may have lost some of its strength.

Disposal

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.

Product description

What it looks like

Allegron 10mg tablets are plain, round, white tablets.

Allegron 25mg tablets are orange round tablets with a scoreline on one side.

Ingredients

Active ingredient:

- Allegron 10 mg tablet contains 10 mg of nortriptyline (as hydrochloride) as the active ingredient.
- Allegron 25 mg tablet contains 25 mg of nortriptyline (as hydrochloride) as the active ingredient.

Inactive ingredients:

Allegron tablets also contains:

- maize starch,
- magnesium stearate,
- lactose monohydrate,
- calcium phosphate,
- glycerol,
- hypromellose

Allegron 25mg tablets also contains

- Sunset Yellow FCF CI15985.

Contains sugars as lactose

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

Sponsor Details

Allegron is supplied in New Zealand by:

Arrotex Pharmaceuticals (NZ) Limited:
C/o Quigg Partners
Level 7, The Bayleys Building
36 Brandon Street,
Wellington 6011, New Zealand

Date of Preparation

This leaflet was prepared in July 2025