

ALLEGRON®

nortriptyline hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet is designed to provide you with answers to some common questions about this medicine. It does not contain all the available information and does not take the place of talking with your doctor.

All medicines have risks and benefits.

Your doctor has more information about this medicine than is contained in this leaflet. Also, your doctor has had the benefit of taking a full and detailed history from you and is in the best position to make an expert judgement to meet your individual needs.

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

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

What ALLEGORON is used for

ALLEGRON is used to treat depression.

There are many different types of medicines used to treat depression. ALLEGORON 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.

Your doctor may have prescribed ALLEGORON for another reason.

Ask your doctor if you have any questions about why ALLEGORON has been prescribed for you.

Before taking ALLEGORON

Tell your doctor if you have any of the following conditions or if you have ever experienced any of these conditions.

When you must not take ALLEGORON

Do not take ALLEGORON

- **if you have had an allergic reaction to any medicines containing nortriptyline or to any of the ingredients listed at the end of this leaflet (see 'Product Description').** Signs of an allergic reaction may include rash, itching of the skin, shortness of breath and swelling of the tongue or face.
- **if you are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI), or have been taking a MAOI within the last 14 days. Check with your doctor or pharmacist if you are unsure as to whether or not you are taking a MAOI.**
- **if you are taking another medicine for sedation or anxiety.** If you take both medicines together, you may have an allergic reaction.
- **if you have an irregular heart beat or have had a heart attack within the previous eight weeks.**
- **if the expiry date on the pack has passed.** If you take this medicine after the expiry date has passed, it may not work as well.

- **if the packaging is torn or shows signs of tampering.**

Before you start taking ALLEGORON

Tell your doctor if you have allergies to any other medicines, including other medicines used to treat your current condition, or other substances such as foods, preservatives or dyes.

Tell your doctor if you are pregnant or intend to become pregnant.

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

Tell your doctor if you are breast-feeding or plan to breast-feed.

It is not known whether ALLEGORON passes into breast milk.

Tell your doctor if you have or have had any medical conditions, especially the following:

- **heart or blood vessel problems**
- **diabetes**
- **glaucoma (increased pressure in the eye)**
- **difficulty in urinating**
- **thyroid problems**
- **epilepsy or seizures**
- **mental illnesses such as mania or schizophrenia**
- **family history of suicide or mania**
- **psychiatric disorder such as suicidal thoughts**

Tell your doctor if you plan to have surgery.

Tell your doctor about these things before you take ALLEGORON.

There is no specific information available to recommend the use of ALLEGORON in children or adolescents under 18 years of age.

Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or health food shop.

Some medicines may affect the way ALLEGORON works. These include:

- cimetidine, a medicine used to treat ulcers and gastric reflux.
- fluoxetine, a medicine used to treat depression.
- quinidine, a medicine used to treat heart disease.
- chlorpropamide, a medicine used to treat diabetes.
- carbamazepine, a medicine used to treat epilepsy.
- medicines used to treat high blood pressure.
- medicines used to treat thyroid problems
- selective serotonin reuptake inhibitors (SSRIs), a group of medicines used to treat depression and other mental illnesses, such as fluoxetine, sertraline and paroxetine. This could result in "serotonin syndrome". This condition may include feeling agitated or restless,

confused, loss of muscle coordination or twitching muscles and shivering

- anticholinergics, found in some medicines used to relieve stomach cramps; travel sickness; hayfever and allergies; cough and colds. This could result in high fever, particularly during hot weather. If you take these medicines together, you may feel drowsier and experience dry mouth, constipation, and dizziness for a longer period of time. Also, you may be more at risk of developing seizures and neuroleptic malignant syndrome. Neuroleptic malignant syndrome may include sudden increase in body temperature, sweating, fast heartbeat, muscle stiffness, high blood pressure and convulsions

Your doctor or pharmacist will be able to tell you what to do when taking ALLEGORON with other medicines.

How to take ALLEGORON

How much to take

Your doctor will tell you how much ALLEGORON you need to take each day. The usual adult dose for ALLEGORON is 75 to 100mg daily, in 3 or 4 divided doses. For elderly patients 25 to 50mg daily in divided doses is recommended. Your doctor may increase or decrease your dose depending on your condition.

How to take it

Tablets should be swallowed whole with a glass of water.

When to take it

ALLEGRON can be taken with or without food.

How long do I take it

For depression, the length of treatment will depend on how quickly your symptoms improve. Most antidepressants take time to work so don't be discouraged if you do not feel better right away. While some symptoms will be relieved sooner than others, ALLEGORON commonly takes two to four weeks before improvement is really apparent.

Continue taking ALLEGORON for as long as your doctor recommends.

If you do not start to feel better in about four weeks, check with your doctor.

If you forget to take it

Take it as soon as you remember, and then go back to taking it as you would normally.

Do not take an extra dose.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not try to make up for missed doses by taking more than one dose at a time.

If you take too much

Taking too much ALLEGORON at once can be dangerous and may cause death.

If you think that you have used too much ALLEGORON, you may need urgent medical attention.

Immediately telephone your doctor or Poisons Information Centre (13 11 26) or go to casualty at your nearest hospital, if you think you or anyone else has 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.

While you are taking ALLEGRON

Things you must do

Tell all doctors and pharmacists who are treating you that you are taking ALLEGRON.

Before you start any new medicine, tell your doctor or pharmacist that you are taking ALLEGRON.

Watch carefully for signs that your depression or anxiety is getting worse, especially in the first few weeks of treatment.

Tell your doctor immediately if you experience any of the following symptoms, especially if they are severe, you have not had these symptoms before or they happen very suddenly:

- anxiety or agitation
- panic attacks
- difficulty sleeping
- hostility or impulsiveness
- restlessness
- overactivity or uninhibited behaviour
- thoughts of suicide

Tell your doctor immediately if you have any thoughts about suicide or doing harm to yourself.

The symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide. These symptoms may continue or get worse during the first one to two months of treatment until the full antidepressant effect of the medicine becomes apparent. This is more likely to occur in children, adolescents and young adults ages 18 to 24.

Warning signs of suicide:

- All thoughts or talk about suicide or violence are serious. If you or someone you know is showing the following warning signs, either contact your doctor or a mental health advisor right away or go to the nearest hospital for treatment.
- Thoughts or talk about death or suicide
- Thoughts or talk about self-harm or doing harm to others
- Any recent attempts of self-harm
- An increase in aggressive behaviour, irritability or agitation.

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

Tell your doctor if you become pregnant while taking ALLEGRON.

Visit your doctor regularly so your progress can be checked.

Tell your doctor if your mouth feels dry and this lasts for more than 2 weeks.

ALLEGRON causes dry mouth.

Things you must not do

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 drive or operate machinery until you know how ALLEGRON affects you.

Do not give ALLEGRON to anyone else. Your doctor has prescribed it specifically for you and your condition.

Things to be careful of

Be careful driving or operating machinery until you know how ALLEGRON affects you.

ALLEGRON may cause drowsiness in some people.

Make sure you know how you react to ALLEGRON before you drive a car or operate any machinery.

Be careful when drinking alcohol while taking ALLEGRON. Combining ALLEGRON and alcohol can make you more sleepy, dizzy or light-headed.

Your doctor may suggest that you avoid alcohol while you are being treated with ALLEGRON.

Be careful to avoid exposure to sunlight while you are taking ALLEGRON, as symptoms of sunburn may occur more quickly than normal.

Some people may suffer symptoms such as nausea, headache or malaise if ALLEGRON is stopped suddenly. Your doctor may decide to reduce your dose, or the interval of your dose over 1 or 2 weeks.

Side effects

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

Like other medicines, ALLEGRON may cause some unwanted side effects. These are likely to vary from patient to patient. Some side effects may be related to the dose of ALLEGRON so it is important that you never exceed the stated dose.

It is important that you tell your doctor as soon as possible about any unwanted effects. Your doctor may then decide to adjust the dose of ALLEGRON you are taking.

Tell your doctor if you notice any of the following side effects and they worry you.

These are common side effects of tricyclic antidepressants.

- Drowsiness, weakness, headache
- blurred vision
- constipation
- diarrhoea and stomach pain
- vomiting
- dizziness or light-headedness (especially on standing rapidly)
- nausea
- difficulty passing urine
- dry mouth

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

- body temperature changes (low and high)
- difficulty in breathing
- increased heartbeat (palpitations) or irregular heartbeats
- hallucinations
- feeling anxious, restless or confused
- tingling or numbness of the hands or feet
- larger breast than normal (in men and women)
- yellowing of the eyes or skin (jaundice)

These side effects are uncommon but may be serious and need urgent medical attention.

There are other rare side effects.

Tell your doctor if you notice any unusual symptoms or if you are concerned about any aspect of your health, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

After taking ALLEGRON

Storage

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.

Keep your tablets in a cool dry place where the temperature stays below 25 degrees C.

All medicines should be kept where young children cannot reach them.

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 your doctor tells you to stop taking ALLEGRON or you find that this medicine has passed its expiry date, ask your pharmacist what to do with any remaining tablets.

Product description

What it looks like

ALLEGRON tablets are available in 2 strengths, 10mg and 25mg.

ALLEGRON tablets are available in packs of 50.

The 10mg tablets are round and white. The 25mg tablets are round and orange with a scoreline on one side.

Ingredients

Active Ingredient - 10mg or 25mg nortriptyline.

Inactive Ingredients - maize starch, magnesium stearate, lactose monohydrate, calcium phosphate, glycerol and hypromellose.

The 25mg tablet also contains Sunset Yellow FCF CI15985.

Both the 10mg and 25mg tablet contain sugars as lactose.

Supplier

ALLEGRON is distributed by:
Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street

Cremorne VIC 3121
www.arrotex.com.au

Australian Registration Numbers:

10 mg: AUST R 14619

25 mg: AUST R 53747

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