

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 ALLEGON?

ALLEGRON contains the active ingredient nortriptyline hydrochloride. ALLEGON is used to treat depression.

For more information, see Section [1. Why am I using ALLEGON?](#) in the full CMI.

2. What should I know before I use ALLEGON?

Do not use if you have ever had an allergic reaction to ALLEGON 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 ALLEGON?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ALLEGON 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 ALLEGON?

- Your doctor will tell you how much ALLEGON you need to take each day.
- The usual adult dose for ALLEGON 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.

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

5. What should I know while using ALLEGON?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using ALLEGON. • Tell your doctor immediately if you have any suicidal thoughts. • Tell your doctor if you become pregnant while taking ALLEGON. • Visit your doctor regularly so your progress can be checked.
Things you should not do	• Do not stop taking ALLEGON, or lower the dose, without checking with your doctor. • Do not give ALLEGON to anyone else.
Driving or using machines	• ALLEGON may cause drowsiness in some people. • Make sure you know how you react to ALLEGON before you drive a car or operate any machinery.
Drinking alcohol	• Be careful when drinking alcohol while taking ALLEGON. Combining ALLEGON 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 ALLEGON.
Looking after your medicine	• 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. • Keep ALLEGON where children cannot reach it.

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

6. Are there any side effects?

Common side effects: 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. Serious side effects include: 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).

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.

ALLEGRON®

Active ingredient(s): *nortriptyline hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ALLEGON. **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 ALLEGON.**

Where to find information in this leaflet:

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

1. Why am I using ALLEGON?

ALLEGON contains the active ingredient nortriptyline hydrochloride. ALLEGON is used to treat depression. There are many different types of medicines used to treat depression.

ALLEGON 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 ALLEGON for another reason.

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

2. What should I know before I use ALLEGON?

Warnings

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

Do not use ALLEGON 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 the packaging is torn or shows signs of tampering.
- **Be careful to avoid exposure to sunlight while you are taking ALLEGON, as symptoms of sunburn may occur more quickly than normal.**
- Some people may suffer symptoms such as nausea, headache or malaise if ALLEGON is stopped suddenly. Your doctor may decide to reduce your dose, or the interval of your dose over 1 or 2 weeks.
- you have a heart condition called Brugada syndrome.
- you have unexplained fainting or a family history of "Brugada Syndrome" or sudden unexplained death due to heart problems.

Check with your doctor if you:

- have any other 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 illness 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 ALLEGON.

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

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.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether ALLEGON 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 affect the way ALLEGON 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. 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 ALLEGON with other medicines

4. How do I use ALLEGON?

How much to take

- Your doctor will tell you how much ALLEGON you need to take each day.
- The usual adult dose for ALLEGON 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.

When to take ALLEGON

- ALLEGON can be taken with or without food.

How to take ALLEGON

- Tablets should be swallowed whole with a glass of water.

How long to take ALLEGON

- 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, ALLEGON commonly takes two to four weeks before improvement is really apparent.
- **Continue taking ALLEGON 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 use ALLEGON

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 use too much ALLEGON

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

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

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you have taken too much ALLEGON 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.

5. What should I know while using ALLEGON?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using ALLEGON.

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

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

Call your doctor straight away 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 should 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.

Driving or using machines

Be careful before you drive or use any machines or tools 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

Drinking alcohol

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.

Looking after your medicine

- 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.

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.

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.

Less serious/Common side effects

Less serious side effects	What to do
• drowsiness, • weakness, • headache, • blurred vision,	Speak to your doctor if you have any of

• constipation, • diarrhoea, • stomach pain, • vomiting, • dizziness or light-headedness (especially on standing rapidly), • nausea, • difficulty passing urine, • dry mouth	these less serious side effects and they worry you.
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Serious side/rare effects

Serious side effects	What to do
• 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), • Brugada Syndrome (unmasking) (symptoms may include very fast or irregular heartbeat, dizziness, fainting, seizures). • low sodium levels in the blood (hyponatraemia). Symptoms may include loss of energy, tiredness, muscle, weakness or cramps, seizures.	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.

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

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What ALLEGRON contains

Active ingredient (main ingredient)	10mg or 25mg of nortriptyline hydrochloride
Other ingredients (inactive ingredients)	• maize starch, • magnesium stearate, • lactose monohydrate, • calcium phosphate, • glycerol, • hypromellose • 25mg tablet also contains Sunset Yellow FCF CI15985.
Potential allergens	Contains sugars as lactose

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

What ALLEGRON looks like

ALLEGRON 10mg tablets are plain, round, white tablets. (Aust R 14619).

ALLEGRON 25mg tablets are orange round tablets with a scoreline on one side. (Aust R 53747).

ALLEGRON 10 mg and 25 mg tablets are available in blister pack of 50 tablets.

Who distributes ALLEGRON

Arrotex Pharmaceuticals Pty Ltd

15 – 17 Chapel Street

Cremorne VIC 3121

www.arrotex.com.au

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