

Package leaflet: Information for the user

Allegron tablets 10mg & 25mg Nortriptyline

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Allegron tablets are and what they are used for
2. What you need to know before you take Allegron tablets
3. How to take Allegron tablets
4. Possible side effects
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1. What Allegron tablets are and what they are used for

Allegron tablets contain the active ingredient nortriptyline hydrochloride, which is a tricyclic antidepressant. Allegron tablets relieve the symptoms of depression.

2. What you need to know before you take Allegron tablets

Do not take Allegron tablets:

- If you are allergic to nortriptyline hydrochloride or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue;
- If you have had a recent heart attack or heartbeat disorder;
- If you have severe liver disease;
- If you suffer from mania (abnormally raised mood);
- If you are breast-feeding;
- If the child is under 6 years of age;
- If you are taking, or have taken in the last two weeks, monoamine oxidase inhibitors (another type of antidepressant);
- If you are taking adrenaline-like drugs including ephedrine, isoprenaline, noradrenaline, phenylephrine and phenylpropanolamine. These drugs are often contained in cough and cold remedies.

Warnings and precautions

Talk to your doctor or pharmacist before taking Allegron tablets

- If you feel suicidal or aggressive - tell your doctor;
- If you are agitated, overactive, or suffer from schizophrenia;
- If you have heart disease;
- If you have a thyroid condition;
- If you have a history of epilepsy;
- If you have high pressure in the eyes (glaucoma);
- If you have an enlarged prostate;
- If your child taking Allegron tablets has a change in behaviour;
- If you are going to have electroconvulsive therapy (electric shock);
- If you are diabetic;

- If you are going to receive an anaesthetic, e.g. for an operation – tell your doctor;
- If you have had an allergic reaction to another tricyclic antidepressant in the past;
- If you are taking medicines containing buprenorphine, including buprenorphine/ naloxone used for treatment of opioid addiction. The use of these medicines together with Allegron tablets can lead to serotonin syndrome, a potentially life-threatening condition (see “Taking other medicines and Allegron tablets”)

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself;
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to hospital straight away.**

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

If any of the above apply to you, tell your doctor or pharmacist.

Taking other medicines and Allegron tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take, any other medicines, including medicines obtained without a prescription.

Some medicines may increase the side effects of Allegron tablets and may sometimes cause very serious reactions. Do not take any other medicines whilst taking Allegron tablets without first talking to your doctor, especially:

- medicines containing buprenorphine, including buprenorphine/ naloxone used for treatment of opioid addiction. These medicines may interact with Allegron tablets and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

The following medicines may interact with your Allegron tablets:

- **guanethidine, debrisoquine, bethanidine, clonidine** (used to treat high blood pressure);
- **barbiturates** (used for anxiety or to make you feel sleepy);
- **alcohol** (you should not drink alcohol);
- **fluoxetine** (another antidepressant);
- **cimetidine** (for heartburn and ulcers);
- **phenothiazines** (for mental illness);
- **carbamazepine** (for epilepsy);
- **propafenone, flecainide, encainide, quinidine** (for heartbeat disorders)
- **valproic acid** (used for the treatment of epilepsy and bipolar disorder).

It may still be all right for you to be given Allegron tablets. Your doctor will be able to decide what is suitable for you.

Pregnancy and breast-feeding

Do not take Allegron tablets if you are breast-feeding.

The safety of nortriptyline for use during pregnancy has not been established. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Nortriptyline hydrochloride may affect alertness. Use caution when driving or operating heavy machinery until you're aware of how this drug affects you. If you feel Allegron tablets affect your ability to drive or use machines, tell your doctor immediately.

Allegron tablets 10mg and 25mg contain lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Allegron tablets 25mg contain sunset yellow (E110)

Sunset yellow (E110) may cause allergic reactions.

3. How to take Allegron tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

Adults:

The usual adult dose is 25mg three or four times daily or the dose may be given once a day, usually at night. The dose should begin at a low level, 10mg, 3-4 times daily, for example and be increased gradually as required. The maximum dose is 150mg per day.

The elderly:

The usual dose is 30 to 50mg/day in divided doses. Treatment may start with 10mg three times a day.

Adolescent patients:

The usual dose is 30 to 50mg/day in divided doses. Treatment may start with 10mg three times a day. Lower dosages are recommended for outpatients than for patients in hospital who will be under close supervision.

Following remission maintenance treatment may be needed longer term. This should be at the lowest dose that stops the symptoms of depression coming back.

Allegron tablets are for oral use.

The score line on the 25mg tablet is only there to help you break the tablet if you have difficulty swallowing it whole.

If you take more Allegron tablets than you should

Go to the nearest casualty department or contact your doctor immediately. Take the tablet carton with you.

If you forget to take Allegron tablets

If you miss a dose, take one as soon as you can. If you have missed several doses, tell your doctor. Do not take a double dose to make up for a forgotten dose.

If you stop taking Allegron tablets

Do not stop taking the tablets or reduce the dose without telling your doctor first.

If you suddenly stop taking the tablets you may feel sick (nausea), have a headache or feel generally unwell.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. **If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

All medicines can cause allergic reactions, although serious allergic reactions are very rare. **Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching, especially affecting your whole body.**

The following side effects have been reported:

- fast or irregular heartbeat
- palpitations
- heart attack (myocardial infarction)
- stroke
- oedema (swelling of the ankles)
- confusion (especially in the elderly) with seeing or hearing things (hallucinations)
- not knowing where you are (disorientation)
- false beliefs (delusions)
- anxiety, restlessness, agitation
- not sleeping (insomnia)
- nightmares
- panic
- long-lasting abnormal mood
- worsening of mental illness
- numbness, tingling, pins and needles in the hands or feet
- coordination problems
- tremors
- abnormal movements
- fits (seizures)
- altered brainwave (EEG) patterns
- ringing in the ears (tinnitus)
- dry mouth
- rarely, inflamed glands under the tongue or inflammation of the gums (gingivitis)
- blurred vision, difficulty in focusing, dilated pupils
- constipation, blockage of the digestive tract
- unable to urinate or delayed urination
- rash
- itching
- light sensitivity
- swelling (oedema)
- fever
- reaction to other similar drugs
- blood disorders which may cause you to bruise easily, become anaemic or be unable to fight off infections
- feeling sick (nausea) and vomiting
- not eating (anorexia)
- indigestion
- diarrhoea
- constipation
- peculiar taste

- inflamed mouth
- abdominal cramps
- black tongue
- development of breasts in men, breast enlargement and milk production in women
- increased or decreased sex drive
- failure to have an erection (impotence)
- swollen testicles
- altered blood sugar levels
- yellow eyes and skin (jaundice)
- altered liver function
- inflamed liver (hepatitis) and liver damage
- weight gain or loss
- sweating
- flushing
- urinating often and at night
- sleepiness
- dizziness
- weakness
- tiredness
- headache
- swollen glands
- hair loss (alopecia)
- An increased risk of bone fractures has been observed in patients taking this type of medicine.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Allegron tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label or carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Allegron tablets contain

The active substance is nortriptyline hydrochloride.
Each tablet contains the equivalent of 10mg or 25mg nortriptyline base.

The other ingredients are:

Tablets 10mg: Maize Starch, Magnesium Stearate, Lactose Monohydrate (see section 2), Calcium Phosphate, Purified Water. *Coat*: Glycerol, Methylhydroxypropyl Cellulose.

Tablets 25mg: Maize Starch, Magnesium Stearate, Lactose Monohydrate (see section 2), Calcium Phosphate, Purified Water, Sunset Yellow (E110) (see section 2). *Coat*: Glycerol, Methylhydroxypropyl Cellulose, Ethylcellulose, Methyl Alcohol, Isopropyl Alcohol, Methylene Chloride.

What Allegron tablets look like and contents of the pack

Tablets 10mg are white, film-coated, unscored and marked 'KING'.

Tablets 25mg are orange, film-coated, scored and marked 'KING'.

Blister strips of 25 tablets or plastic bottles containing 500 or 100 x tablets 10mg or tablets 25mg.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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