PACKAGE LEAFLET

Package leaflet: Information for the user

Amantadine hydrochloride Renata 100 mg Capsules, hard
Amantadine hydrochloride

The name of your medicine is Amantadine hydrochloride Renata 100 mg Capsules, hard, which will be referred to as Amantadine throughout this document.

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 Amantadine is and what it is used for

Amantadine is a dopaminergic drug which means it can increase the levels of certain chemicals which transmit impulses in the nervous system, including the brain.

Amantadine is used to treat Parkinson's disease by improving muscle control, reducing stiffness, shakiness and shuffling, and improving mobility.

2. What you need to know before you take Amantadine

Do not take Amantadine:
- if you are allergic to amantadine hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from a seizure disorder (epilepsy), which cannot be properly treated
- if you have a severe mental illness, in which the control over your own behaviour and actions is disturbed (psychosis).

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take Amantadine.

Warnings and precautions
Talk to your doctor or pharmacist before taking Amantadine if:
- you have seizure disorder (epilepsy)
- you have had thoughts of suicide or harming yourself
- you suffer from any liver or kidney disease
- you have a history of disease involving the heart and blood vessels
- you are currently suffering from heart problems or heart failure (heart problems which cause shortness of breath or ankle swelling)
- you have or have had a stomach ulcer
- you have or have had recurring skin problems (eczema)
- you have low blood pressure

- you have any mental illness for example, schizophrenia or dementia
- you have certain hormonal disorders
- you have untreated increased pressure in the eyes (glaucoma).

Tell your doctor if you or your family/carer notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse control disorders and can include behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or an increase in sexual thoughts or feelings.
Your doctor may need to adjust or stop your dose of Amantadine.

If blurred vision or other visual problems occur please contact an eye doctor immediately.

If you want to stop taking this medicine, contact your doctor first. It may be necessary to taper off the use of this medicine slowly to avoid side effects and not to worsen Parkinson's symptoms (see also section 3 *"If you stop taking this medicine").*

Children
This medicine is not suitable for use in children.

Other medicines and Amantadine
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Especially tell your doctor or pharmacist if you are taking any of the following medicines as they may interfere with Amantadine:
- anti-cholinergics - (used to treat Parkinson's disease) such as procyclidine
- anti-spasmodics - (used to treat stomach spasms or cramps) such as hyoscine
- levodopa - used to treat Parkinson's disease
- anti-psychotics - (used to improve thoughts, feelings and behaviour when these are disturbed in certain medical conditions) such as chlorpromazine, haloperidol
- diuretics (water tablets) - (used to relieve water retention and reduce high blood pressure) such as hydrochlorothiazide, amiloride or triamterene.

Amantadine with alcohol
Alcohol can increase the side effects of this medicine. Therefore, you should not consume alcohol during treatment with this medicine.

Pregnancy, breast-feeding and fertility
If you are pregnant, trying to become pregnant or are breast-feeding, talk to your doctor or pharmacist before taking this medicine.
If you could become pregnant, you should use a reliable birth control method during treatment and for 5 days after the last dose of this medicine. If you become pregnant or wish to become pregnant during treatment with this medicine, you must inform your doctor. Your doctor will determine whether you can take this medicine.
The active substance of Amantadine is excreted in breast milk, which can have an effect on the baby. Therefore, you should not breastfeed while taking this medicine.

Driving and using machines
Taking Amantadine may make your vision blurred or can cause dizziness, confusion, or difficulty concentrating and affect your ability to react. If you are affected you should not drive or use machines until the effect has worn off.

Amantadine contains lactose
This medicine contains lactose (a kind of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Amantadine

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

The dose is determined individually by the doctor. You must follow the prescribed dose exactly. This gives you the best outcomes and reduces the risk of side effects.

Swallow the capsules whole with a drink of water.
Take this medicine after a meal, preferably in the morning. In the case of two intakes per day, a dose should also be taken in the afternoon after a meal.

The recommended dose is:

Take 1 capsule (100 mg) a day at the start of treatment. After at least one week, your doctor will increase this to 2 capsules a day (200 mg) (1 capsule twice a day).

Use in patients 65 years of age and older
Elderly patients are particularly sensitive to the effects of this medicine. Your doctor will give you special instructions if necessary. In older people without kidney dysfunction, a maintenance dose of no more than 100 mg per day (1 capsule) is recommended.

Use in patients with impaired renal function
Patients with impaired renal function usually require a lower maintenance dose. This can be achieved by extending the period between two intakes of 100 mg of this medicine (1 capsule), depending on the severity of the kidney disease. Your doctor will give you special instructions if necessary.
If you are already taking this medicine for the treatment of Parkinson's disease and during your treatment, the kidneys are found to be impaired, your doctor will adjust the maintenance dose depending on the severity of the kidney disease.

Use in children
This medication is not suitable for use in children.

If you take more Amantadine than you should
If you accidentally take too many capsules, or someone else takes any of your medicine, you should tell your doctor at once or contact the nearest accident and emergency department. Show any left-over medicines or the empty packet to the doctor.

The following symptoms may occur if you or someone else has taken too much of this medicine: increase in reflexes (hyperreflexia), physical restlessness, fits, certain types of spasms (torsional spasms), disturbances in muscle tone, aggression/hostility, decreased consciousness and coma, enlarged pupils, cardiac arrest, sudden cardiac death, confusion, disorientation, perception of images that are not there (visual hallucinations), increased blood pressure (hypertension), hyperventilation, difficulty breathing, increased heart rate, cardiac arrhythmia, nausea, vomiting, dry mouth, constipation, decreased urination (urinary retention).

If you forget to take Amantadine
Do not worry. If you miss a dose, take another as soon as you remember, unless it is almost time for your next dose (for example, within 2 to 3 hours). Then go on as before. **Do not take a double dose to make up for a forgotten dose.**

If you stop taking Amantadine
Do not stop taking Amantadine suddenly as your symptoms may get worse.
If you want to stop taking Amantadine ask your doctor who will tell you how to reduce the dose gradually.
Suddenly stopping treatment may worsen your illness, cause a change in your mental status (for example, confusion or disorientation), or lead to a potentially life-threatening condition (similar to

Neuroleptic Malignant Syndrome), which requires immediate medical attention. Neuroleptic Malignant Syndrome is a serious disorder, which can manifest itself as muscle stiffness, strong urge to move, high fever, sweating, salivation, reduced consciousness. **Tell your doctor immediately** if you experience **muscle stiffness and an increased temperature or fever** after suddenly stopping treatment with this medicine, as these symptoms may indicate such a condition (see also section 2 *"What you need to know before you take Amantadine"*).

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.
These effects are often mild and may wear off after a few days treatment. If they are severe or last more than a few days, tell your doctor or pharmacist.

Some side effects can be serious. If you experience any of the side effects listed below, contact your doctor immediately:

Uncommon side effects (that affect less than 1 person in 100):
- perceptions of things that are not there (hallucinations)
- feeling down (depression)
- anxiety
- stammering or stuttering (dysarthria)
- coordination problems (ataxia).

Rare side effects (that affect less than 1 person in 1,000):
- severe confusion or disorientation
- severe mental illness in which control over one's own behaviour and actions is disturbed (psychosis)
- movement disorder (dyskinesia)
- seizures or fits (convulsions)
- abnormalities of the cornea (corneal lesion), fluid retention in the cornea (corneal oedema), impaired visual acuity
- skin rash
- urine retention in the bladder due to the inability to empty the bladder properly (urinary retention)
- inability to control urine (incontinence).

Very rare side effects (that affect less than 1 person in 10,000):
- a serious disorder which may manifest itself as muscle stiffness, strong urge to move, high fever, perspiration, salivation, impaired level of consciousness (symptoms similar to Neuroleptic Malignant Syndrome)
- heart failure
- increased susceptibility to infections (with symptoms such as fever, sore throat, blisters in the mouth) due to a reduced white blood cell count (leukopenia).

Not known (frequency cannot be estimated from the available data):
- acute mental disorder with symptoms such as impaired attention, confusion, memory problems, delusions (delirium)
- excessive excitement that manifests itself in having a lot of energy (mania) or a lighter form of it (hypomania)
- sharp drop in body temperature (hypothermia).

Other side effects:

Common side effects (that affect less than 1 person in 10):
- fluid retention in the legs
- disturbance of attention

- reticulated, blotchy discolouration of the skin, especially on the arms and legs (livedo reticularis).

Uncommon side effects (that affect less than 1 person in 100):
- restlessness (agitation)
- nervousness
- mood enhancement
- dizziness
- light-headedness
- headache
- insomnia
- nightmares
- somnolence (lethargy)
- blurred vision
- atrial flutter (palpitations)
- drop in blood pressure due to, for example, getting up quickly from a sitting or lying position, sometimes accompanied by dizziness (orthostatic hypotension)
- dry mouth
- decreased appetite
- excessive sweating
- nausea
- vomiting
- constipation (obstruction).

Rare side effects (that affect less than 1 person in 1,000):
- shaking (tremor)
- diarrhoea.

Very rare side effects (that affect less than 1 person in 10,000):
- increase in liver enzymes
- hypersensitivity to light or sunlight (photosensitivity reaction).

Not known (frequency cannot be estimated from the available data):
- Urge to behave in an unusual way - strong impulse to gamble excessively, altered or increased sexual interest, uncontrollable excessive shopping or spending, binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger).

If any of the side effects gets worse, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie
Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Amantadine

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 blister and/or carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30˚C.

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

6. Contents of the pack and other information

What Amantadine contains
The active substance is amantadine hydrochloride. Each capsule contains 100 mg amantadine hydrochloride.
The other ingredients are lactose monohydrate, povidone and magnesium stearate.
Capsule shell contains: gelatin, iron oxide black (E172), iron oxide red (E172) and titanium dioxide (E171).
Capsule printing ink contains: shellac, black iron oxide (E172) and potassium hydroxide (E525).

What Amantadine Capsule looks like and contents of the pack
Amantadine is hard gelatin capsule (size "4", 14 mm), cavern pink cap printed "RENATA" in black and cavern pink body printed "AMCL" in black containing white crystalline powder.

Amantadine is available in blister pack containing 12, 14, 24, 28 and 56 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Renata Pharmaceuticals (Ireland) Limited
12 Crowe Street, Dundalk, Co. Louth, Ireland, A91 NN29

Manufacturer
Alterno Labs d.o.o., Brnčičeva ulica 29, Ljubljana-Črnuče, 1231, Slovenia.

Distributed by
Azure Pharmaceuticals Ltd, Blackrock, Co. Louth, Ireland.

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland	Amantadine hydrochloride Renata 100 mg Capsules, hard
Malta	Amantadine hydrochloride Renata 100 mg Capsules, hard

This leaflet was last revised in May 2024.