

PACKAGE LEAFLET: Information for the user

AMANTADINE

Tablets – 100 mg

(Amantadine hydrochloride)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Amantadine is and what it is used for
2. Before you take Amantadine
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4. Possible side effects
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1. WHAT AMANTADINE IS AND WHAT IT IS USED FOR

Amantadine is a weak dopamine agonist, with mild antiparkinsonian activity.

Its exact mechanism of action is not fully understood but it is supposed that it helps the release of dopamine from the intact dopaminergic neuronal ends, which are located in *substantia nigra* in the parkinsonian patients. Amantadine is less effective than levodopa in the treatment of parkinsonism, but a little bit more effective than the other anticholinergic drugs. It may improve bradykinesia, muscle rigidity and tremor but tolerance can develop.

This medicine exerts an antiviral effect against influenza type A2 virus.

Amantadine is indicated in:

- Parkinson disease;
- drug-induced extrapyramidal symptoms and syndrome;
- postencephalytic parkinsonism;
- arteriosclerotic parkinsonism;
- symptomatic parkinsonism after trauma of the nervous system from carbon monoxide poisoning.

Usually it is combined with other antiparkinsonic drugs.

Amantadine is indicated also in the prophylaxis and treatment of infections caused from influenza virus type A2, but it is ineffective in the treatment of infections caused from other types of viruses; it is used in the treatment of herpes zoster.

Your doctor may have given Amantadine for a different purpose. Ask your doctor if you want to know why you were given this medicine.

2. BEFORE YOU TAKE AMANTADINE

Do not take Amantadine if:

- you are allergic to amantadine hydrochloride;
- you are allergic to any of the excipients mentioned at the end of this leaflet;
- you are pregnant or you are planning to become pregnant;
- you are breastfeeding your baby;
- you suffer from epilepsy;
- you have gastric ulceration;
- you have severe renal disease;
- you have untreated closed-angle glaucoma.

If you think that you suffer from any of the conditions mentioned above, do not take the tablets. Consult your doctor and then follow the given advice.

Take special care with Amantadine

Tell your doctor if:

- you are allergic to other medicines, especially if they are in the same class of drugs as amantadine;

- if you have or have had any health problems, in particular the following:

cerebral atherosclerosis, particularly the elderly, you are treated with stimulants of the central nervous system, renal failure, congestive heart failure, cardiovascular disease or liver disease, recurrent eczema, peripheral edema.

Caution is required in elderly patients, who may be more sensitive to antimuscarinic effects and in whom renal clearance is likely to be reduced.

Suicide attempts, in some cases fatal, and suicidal ideation have been reported in patients taking amantadine. 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. Treatment with amantadine should not be stopped abruptly in parkinsonian patients since they may experience a sudden marked clinical deterioration.

If you experience blurred vision or other vision problems, contact your ophthalmologist immediately.

Taking other medicines

Inform your doctor or pharmacist if you are taking or have recently taken other medicines, even those without a prescription. Inform your doctor if you are taking any of these drugs:

- anticholinergics, because amantadine can potentiate their side effects and thus confusion and hallucinations may appear, so during concomitant use, the dose of anticholinergics needs to be reduced. Your doctor or pharmacist will advise you;
- antihypertensives, methyldopa causes extrapyramidal side effects;
- domperidone and metoclopramide: they cause extrapyramidal side effects;
- medicines that affect the CNS;
- levodopa, since amantadine can potentiate its side effects;
- drugs which increase the urinary pH, because the excretion rate of amantadine may be reduced.

In isolated cases, interactions between amantadine and a combination of diuretics (hydrochlorothiazide combined with potassium-sparing diuretics) were reported. It seems that one of them or both reduce the clearance of amantadine, thus increasing its plasma

concentrations and toxic effects (confusion, hallucinations, ataxia, myoclonia).

Taking Amantadine with food and drinks

Be careful when drinking alcohol whilst taking Amantadine since it may affect you more than usual.

Pregnancy and breastfeeding

Inform your doctor or pharmacist if you are pregnant or are planning to get pregnant, because amantadine should not be used during pregnancy.

Amantadine passes into breastmilk, so it should not be used during breastfeeding.

Driving and using machines

Be careful when driving or using machinery until you see how Amantadine affects you.

Amantadine can cause drowsiness or dizziness or blurred vision in some patients, especially after taking the first dose.

Important information about some of the excipients of Amantadine

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

3. HOW TO TAKE AMANTADINE

Always take Amantadine tablets as your doctor has advised you. If you feel that the effects of amantadine are too strong or too weak, talk to your doctor or pharmacist.

It is advised to take the tablets at the same time every day.

The recommended dose in *Parkinson's disease*: 100 mg, twice daily, when used as a single drug.

Initial dose: 100 mg / day, if the patient is weakened or takes high doses of other antiparkinsonic drugs. If needed, a maximum of 400 mg per day may be taken.

Extrapyramidal reactions caused by drugs: 100 mg, twice daily; it may be given up to 300 mg per day in divided doses.

Viral infections of influenza A (symptomatic treatment):

Adults, 200 mg per day as a single dose or 100 mg, twice daily.

The elderly and patients who previously have had contraction disorders: 100 mg, every day.

Children 10-15 years: 100 mg, once daily.

Viral infections of influenza A (prophylaxis): Doses are the same as those for symptomatic treatment.

Herpes zoster infections: 100 mg, twice daily for 14 days, which in case of emergency may be extended with other 14 days for postherpetic neuralgia.

Your doctor may ask you to take Amantadine for a longer time. Ask your doctor for advice if you are not sure for how long you should take it.

Amantadine tablets should be swallowed with a full glass of water.

If you take more Amantadine than you should

If you take more Amantadine than you should, or if the children have wrongly taken this drug, please contact your doctor, hospital, or call the emergency to get an opinion on the risk and advice on the actions to be taken.

If you forget to take Amantadine

If you forget a dose, take the following dose when it is time to take it usually.

Do not take a double dose to make up for the forgotten dose. If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

If you stop taking Amantadine

Treatment with Amantadine should not be stopped abruptly, cause a sudden deterioration of the clinical conditions may appear.

If you are taking anti-psychotics (used to treat mental disturbances) and you suddenly stop taking Amantadine, you may develop a collection of symptoms including: fever, sweating, a rapid heart beat, muscle stiffness (difficulty in movement), loss of bladder control (you may have a sudden urge to pass water).

If you develop any of these symptoms you should contact your doctor immediately. Some patients may notice that this medicine loses its effect after they have taken it regularly for a few months. If you notice this, tell your doctor.

4. POSSIBLE SIDE EFFECTS

All medicines may cause side effects. Sometimes they are serious, most of the times not. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Inform your doctor if any of the following side effects bothers you:

digestive disorders, lack of appetite, nausea, vomiting, diarrhea, constipation, dry mouth; nervous excitement, difficulty concentrating, dizziness, speech disorders, tremor, ataxia, insomnia, headache, depression, hiccup, erythema, edema of the legs, livedo reticularis, palpitations, orthostatic hypotension, urinary retention, anxiety, nightmares, mood disorders, leucopenia, diaphoresis, exanthema, photosensitization, corneal damage, Neuroleptic Malignant-like Syndrome.

Psychotic reactions have been reported, hallucinations and confusion, mainly among the elderly, those with renal impairment or with psychiatric disorders and those who concomitantly take antimuscarinics.

These effects are reversible and disappear with the cessation of treatment. Doses four times higher than those recommended, can cause convulsions.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE AMANTADINE

Keep out of the reach and sight of children.

Do not use Amantadine after the expiry date stated on the package.

Do not store above 25 °C.

6. FURTHER INFORMATION

What Amantadine 100 mg tablets contain

The active substance is Amantadine hydrochloride.

One tablet contains 100 mg of amantadine hydrochloride.

The excipients are: lactose, magnesium stearate, starch, gelatin, sodium starch glycolate.

Content of the pack

Box with 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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