

Information pamphlet for the user
Amantadine Level 100mg tablets
Amantadine (amantadine hydrochloride)

Read the whole of this prospectus in detail, because it contains information that will be important to you.

This medication can be obtained without a prescription for the treatment of minor afflictions without the intervention of a doctor. However, you must use Amantadine Level with care to obtain the best results.

-Keep this prospectus; you may need to read it again.

-If you have any doubts, consult your doctor or pharmacists.

This medicine has been prescribed to you and must not be given to others. It may harm them, even when their symptoms are the same as yours.

In this prospectus:

1. What are Amantadine Level and what are they used for?
2. Before using Amantadine Level
3. How to use Amantadine Level
4. Possible adverse effects
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1 What is Amantadine Level and what is it used for?

Amantadine is a medicine that belongs to a group of medicines known as dopamines, it can work as an anti-viral or anti-Parkinson's drug and it is used with adults and children older than 10 to:

- Treat the symptoms of the flu caused by the *Influenza A* virus, when the virus (*Influenza A*) is circulating in the community.
- Prevent flu when the virus (*Influenza A*) is circulating in the community.
- Treat the symptoms of Parkinson's disease, such as rigidity, trembling, hypokinesia and akinesia (difficulties of movement).

Amantadine Level is not a substitute for the flu vaccine. You will need to see your doctor to be assessed as to the necessity of administering the vaccine.

2 Before taking Amantadine Level

Do not take Amantadine Level

-If you are allergic (hypersensitive) to amantadine, rimantadine, or any of the other components of Amantadine Level.

- If you suffer from or have suffered from cardiac illnesses (for example cardiac insufficiency, myocarditis, bradycardia, serious ventricular arrhythmias, including *torsade de pointes*).

-If you suffer from prolongation in the QT interval or if you have relatives with a history of the congenital QT syndrome (a defect of the heart's electric system which can produce an abnormal cardiac rhythm).

- If you are being treated with budipine or other medicines or other drugs that provoke change in the electrocardiogram.
- If you are pregnant or breast feeding.
- If you suffer from convulsions.
- If you suffer or have suffered from bleeding in the stomach (gastric ulcer).
- If you don't produce or produce very little urine (serious renal failure).
- If you have increased pressure in the eye (closed angle glaucoma).

Be especially careful with Amantadine Level

Before starting treatment with Amantadine Level, be especially careful

- If you have enlargement (hypertrophy) of the prostate.
- If you suffer from a disorder in the kidneys or liver (renal or hepatic insufficiency) your doctor will adjust the dose.
- If you have found yourself agitated, confused or had hallucinations.
- If you suffer from or have a history of epilepsy (chronic illness in the brain), or psychiatric disorders such as becoming delirious.
- If you are having treatment with memantine (used to treat the symptoms of Alzheimer's).
- If you suffer from or have suffered from any heart problems then you must consult with your doctor so the dose can be regulated.
- If you suffer from organic cerebral syndrome (decrease in brain functioning) or if you have a propensity to dizziness.
- If you suffer from orthostatic hypotension (decrease in blood pressure caused by a sudden change in the body's position) or peripheral edema (abnormal accumulation of liquid in the ankles, feet and legs provoking swelling in these areas).
- If you suffer from eczema or skin rashes. In some cases Amantadine can aggravate this situation.

During treatment for Parkinson's with amantadine the supplementary administration of amantadine in the prophylaxis and treatment of influenza A is not recommended, due to the risk of overdose.

Use of other medicines

Inform your doctor or pharmacist if you are using or have recently used other medicines, including those acquired without prescription.

Bear in mind that these instructions may be applicable to medicines which have been taken before or may be taken later.

The simultaneous use of amantadine and other medicines that cause an increase of the QT interval is contraindicated, as in the following cases:

- medicines used to suppress or prevent alterations in the cardiac rhythm (anti-arrhythmics) such as class A anti-arrhythmics (eg. quinidine, disopyramide, procainamide) and class III (eg. amiodarone, sotalol).
- antipsychotics and major tranquilisers (eg. tioridazine, chlorpromazine, haloperidol, pimozide).

- tricyclic and tetracyclic anti-depressives (eg. amitriptyline)
- anti-histamines, they help to treat symptoms of allergies (eg. astemizole, terfenadine).
- macrolide antibiotics (eg. erythromycin, clarithromycin).

Some quinolones which are a particular type of antibiotic (eg. sparfloxacin, grepafloxacin).

- medicines used for infections with fungi (antimycotic) specifically those called azoles.
- other medicines such as halofantrine and quinine (used to treat malaria) cotrimoxazole (a combination of trimethoprim and sulfamethoxazole, used as an antibiotic), pentamidine (anticoagulant used in the treatment of certain infections), cisapride (gastrointestinal prokinetic agent indicated for the treatment of gastroesophageal reflux) and bepridil (blocker of the calcium channels. It is used to alleviate and control angina pectoris.)

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The administration of amantadine in combination with other anti-Parkinson's drugs (eg. levodopa, memantine, bupropion) is possible. Although to avoid adverse reactions it may be necessary to reduce the dose of some of the medicines or the combination.

Other medicines that can work with amantadine exist and they are the following:

- Anticholinergics have many clinical uses such as antispasmodics, bronchodilators, in Parkinson's in ophthalmology... (trihexyphenidyl, benztropine, scopolamine, biperiden, orfenadrine etc).
- SNC sympathomimetics, medicines that stimulate psychic functions (like conscience, orientation, attention or concentration), increasing the levels of motor activities (or movement) and cognitive (or knowledge), as well as attention.
- Diuretics (medicines used to increase the elimination of urine) such as hydrochlorothiazide or furosemide.
- You must avoid taking trimethoprim (antibiotic).

Taking Amantadine Level with food and drink

It is recommended not to drink alcohol when being treated with Amantadine Level, it can have an effect on the nervous system such as dyskinesia (involuntary movements), confusion, fainting, and orthostatic hypertension.

Pregnancy and breast feeding

Speak to your doctor or pharmacist before using any medicine.

It is recommended not to use Amantadine Level if you are pregnant or breast feeding.

Driving and operating machinery

Do not drive or use tools or machines as Amantadine Level produces adverse reactions with certain frequency (eg. drowsiness, visual distortions, vertigo, dizziness) which could reduce your capacity to concentrate or react.

How to take Amantadine Level

Follow the administration instructions given by your doctor exactly. Consult with your doctor or pharmacist if you have doubts.

Remember to take your medicine.

Your doctor will indicate the duration of your treatment with Amantadine Level. Do not suspend your treatment without first consulting with your doctor.

A stronger dose may be administered according to facultative judgement and with the patients under strict medical control.

If you feel that the effect of Amantadine Level is too strong or weak, tell your pharmacist or doctor.

Amantadine Level is administered **orally**.

Treatment of flu

-One tablet (100mg of amantadine hydrochloride) twice a day.

Do not exceed the dose of 200mg/day (two tablets a day).

Flu prophylaxis

One tablet (100mg of amantadine hydrochloride) twice a day.

The start and duration of the treatment will be decided by your doctor on an individual basis, for the length of time necessary to protect oneself from the infection for a maximum of 6 weeks.

When it is administered in conjunction with the inactivated *influenza A* vaccine the treatment will be continued for 2-4 weeks after inoculation.

Treatment of Parkinson's

-The treatment will start with 100mg daily for the first week, and then continue with a tablet (100mg of amantadine hydrochloride) twice a day.

Do not take more than 4 tablets a day (400mg).

Method of administration

Amantadine Level tablets must be taken with a little liquid.

Amantadine produces insomnia (difficulty sleeping) with certain frequency. Try to adjust the dosage cycle so that the last dose is not administered late in the evening or at night. When treating patients with Parkinson's it is necessary to start gradually and not suspend the treatment suddenly.

Patients with renal insufficiency

It will be administered to these patients with great care. In these cases the doctor will adjust the dosage depending on the lightening of creatinine (a laboratory test which evaluates the working of the kidneys) of the patient.

Use with elderly patients

These patients can be more susceptible to the effects of amantadine, so the dose used must be the lowest possible.

Use with children

Children older than 10: One tablet (100mg of amantadine hydrochloride) a day. Its use in children of less than 10 years old is not recommended as experience is limited with this group of the population.

If you take more Amantadine Level than you should

Consult your doctor or pharmacist immediately.

The symptoms of an overdose are: nausea, vomiting, hyper-excitability, trembling, uncontrolled movements (ataxia), blurred vision, drowsiness, depression, problems speaking (dysarthria) and convulsions. It can also cause irregular heartbeats (arrhythmias), retention of liquid in the lungs (pulmonary edema), repeated convulsions (*status epilepticus*), and toxic psychosis (a state of confusion that can end in coma).

In the case of overdosing vomiting should immediately be induced and/or a stomach pump. No specific antidote exists. The elimination of the medicine shall be tried via the acidification of the urine and a symptomatic treatment shall be installed, including, if needed, the use of sedatives and anti-convulsives.

In the case of an overdose or accidental ingestion, immediately consult your doctor or pharmacist or phone the Toxicological Information Service on 915620420, indicating the medicine and the amount used. It is recommended to take the medicine and information pamphlet to professional health staff.

If you forget to take Amantadine Level

Do not double the dose to compensate the forgotten ones. It is best to take the dose as soon as possible.

If you interrupt the treatment with Amantadine Level

If you suffer from Parkinson's you must avoid the sudden stopping of the treatment. It can cause a rebound effect with the apparition of rigidity, confusion or bulbar paralysis. If you have any other doubt about this product ask your doctor or pharmacist.

4. Possible side effects

As with all medicines Amantadine Level can produce side effects, although not everyone suffers from them.

If you consider any of the adverse effects to be serious or if you feel any side effect not mentioned in this pamphlet, inform your doctor or pharmacist.

-Very frequent (1 in every 10 patients treated): Edema in the legs, red or blue stains on the skin called 'livedo reticularis' (generally after high doses).

-Frequent (between 1 and 10 in every 100): Drowsiness or insomnia, depression, states of agitation, vertigo, headaches, hallucinations, confusion, dizziness, lethargy

(continued deep tiredness that is often accompanied by muscular relaxation), nightmares, uncoordinated movements (ataxia), difficulty speaking, lessening of the blood pressure produced by a sudden change of position (orthostatic hypertension), palpitations, dry mouth, nausea, loss of appetite (anorexia), vomits, constipation, sweating, blurred vision, myalgia (muscular pain).

-Rare (between 1 and 10 of every 1000): Convulsions, disorientation, psychosis (altered mental state), trembling, abnormal movements (discinesia), neuroleptic syndrome (among other symptoms it causes an altered state of consciousness), diarrhea, cutaneous eruptions, corneal injury, urinary retention or incontinence.

-Very rare (1 every 10000): lessening of the white blood cells (leucopenia), reversible increase in hepatic enzymes, congestive cardiac insufficiency, cardiac failure, photosensitivity.

All the side effects cease when you halt the treatment and the majority disappear after a few days of continued therapy.

5. Conservation of Amantadine Level

Keep out of sight and reach of children.

Do not use Adrenaline Level after the expiry date that appears on the container. The date of expiry is the last day of the month indicated.

You do not need to take any special care of Adrenaline Level. Conserve it in its original container.

Medicines must not be disposed of in the drains or thrown away. Ask your pharmacist how to dispose of any containers or unneeded medicines. This way you will help look after the environment.

6 Additional information

Composition of Amantadine Level

-The principal ingredient is amantadine (amantadine hydrochloride). Each tablet contains 100 mg of amantadine hydrochloride.

-The remaining ingredients are dehydrated dicalcium phosphate, magnesium stearate and carboxymethyl cellulose. The gelatine tablet is composed of gelatine, indigo carmin (E132), yellow quinoline (E104) and titanium dioxide (E171).

Appearance of Amantadine Level and pack contents

Amantadine Level is a medicine that is presented in the form of hard tablets. Each packet contains 20 tablets.

Holder of the authorisation for the commercialisation and fabrication of the product.

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This information prospectus was approved in November 2010.