

Amantadine Hydrochloride

50 mg/5 ml Oral Solution

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

- What Amantadine Oral Solution is and what it is used for
- What you need to know before you take Amantadine Oral Solution
- How to take Amantadine Oral Solution
- Possible side effects
- How to store Amantadine Oral Solution
- Contents of the pack and other information

1. What Amantadine Oral Solution is and what it is used for

Amantadine Oral Solution 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 Oral Solution is used:

- to treat Parkinson's disease by improving muscle control and reducing stiffness, shakiness and shuffling.

2. What you need to know before you take Amantadine Oral Solution

Do not take Amantadine Oral Solution:

- if you are allergic to amantadine hydrochloride or any of the ingredients of Amantadine Oral Solution (listed in Section 6)
- if you suffer from fits (convulsions), for example epilepsy
- if you have ever had an ulcer in your stomach or small intestine
- if you suffer from any serious kidney disease
- if you are pregnant or trying to become pregnant (see Section 2 Pregnancy and breast-feeding).
- if you are breast-feeding (see Section 2 Pregnancy and breast-feeding).

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

Warnings and precautions

Talk to your doctor before you take Amantadine Oral Solution tell your doctor if:

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

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take Amantadine Oral Solution. Abnormally low body temperatures (below 35°C) can occur particularly in children treated for influenza. In this case talk to your doctor straight away and stop taking Amantadine Oral Solution. 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 hydrochloride.

Cases of suicidal thoughts and actions have been reported during treatment with amantadine. If you have thoughts or attempts of harming or killing yourself, contact your doctor immediately.

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

Other medicines and Amantadine Oral Solution

Tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines as they may interfere with Amantadine Oral Solution:

- anti-cholinergics - (used to treat Parkinson's disease) such as procyclidine
- anti-spasmodics - (used to treat stomach spasms or cramps) such as hyoscine
- anti-histamines - used to treat allergies
- 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.

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

Taking with food, drink and alcohol

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

Pregnancy and breast-feeding

Do not take Amantadine Oral Solution if you are pregnant or trying to become pregnant.

Do not take Amantadine Oral Solution if you are breast-feeding because Amantadine passes into breast milk and could harm your baby.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Taking Amantadine Oral Solution may make your vision blurred or make you feel dizzy. If you are affected you should not drive or use machines until the effect has worn off.

Amantadine Oral Solution contains Sorbitol, Methyl and propyl hydroxybenzoate

This medicine contains 3.255 g sorbitol per dose of 5mL. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect. Methyl hydroxybenzoate (E218) and propyl hydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

3. How to take Amantadine Oral Solution

Always take this medicine exactly as your doctor has told you to.

You should check with your doctor or pharmacist if you are not sure. Shake the bottle before carefully measuring out your dose.

The usual dose is different in the following circumstances:

The recommended dose in Parkinson's disease:

Adults: Two 5ml spoonfuls (100 mg) a day for the first week. Your doctor will increase this to four 5ml spoonfuls (200 mg) a day. Higher doses, up to eight 5ml spoonfuls (400 mg) a day may be given in some cases.

Adults over 65 years: Two 5ml spoonfuls (100 mg) once a day.

If you have kidney problems, your doctor may give you a lower dose.

What to do if you take more Amantadine Oral Solution than you should

If you accidentally take too much solution, 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 bottle to the doctor.

If you forget to take Amantadine Oral Solution
Do not worry. If you miss a dose, take another as soon as you remember, unless it is almost time for your next dose. Then go on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Amantadine Oral Solution
Do not stop taking Amantadine Oral Solution suddenly as your symptoms may get worse.
If you want to stop taking Amantadine Oral Solution ask your doctor who will tell you how to reduce the dose gradually.
If you are taking anti-psychotics (used to treat mental disturbances) and you suddenly stop taking Amantadine Oral Solution, 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. If you have any further questions on the use of this product, 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.

If any of the following symptoms occur you should tell your doctor or contact the nearest hospital straight away:

- dizziness or light-headedness,
- fainting,
- convulsions (fits).

Tell your doctor or pharmacist if you think you have any of these or other problems with Amantadine Oral Solution:

Very Common side effects (may affect more than 1 in 10 people)

- swollen ankles,
- red blotchy spots on the skin.

Common side effects (may affect up to 1 in 10 people)

- loss of appetite
- confusion
- anxiety
- depression
- feeling tired
- feeling overexcited
- hallucinations
- difficulty in controlling movements
- low blood pressure when standing up. This may make you feel dizzy or faint
- feeling or being sick
- difficulty concentrating
- feeling nervous
- difficulty sleeping
- muscle pain
- headache
- nightmares
- slurred speech
- fast or irregular heartbeat
- dry mouth
- constipation
- sweating

Uncommon side effects (that affect less than 1 person in 100):

- blurred vision

Rare side effects (that affect up to 1 in 1000 people)

- convulsions (fits)
- disturbed thoughts or behaviour such as feeling paranoid
- Neuroleptic Malignant Syndrome (NMS). You may feel hot and have muscle stiffness
- loss of bladder control. You may have difficulty in passing water or have a sudden urge to pass water

- disorientation (not knowing where you are)
- shakiness
- difficulty moving
- diarrhoea
- skin rash
- problems with your eyes such as itchiness or redness
- corneal lesion, corneal oedema, reduced visual acuity

Very rare side effects (that affect less than 1 person in 10 000)

- heart problems which cause shortness of breath or ankle swelling,
- reduction in the number of white blood cells which makes infections more likely,
- changes in blood tests which show how the liver is working,
- sensitivity to sunlight.

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)
- Quick, involuntary muscle jerk
- Abnormally low body temperature (below 35°C) has been observed especially in children.

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 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 Amantadine Oral Solution

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 packaging.
The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

If your doctor decides to stop your treatment, return any unused medicine to the pharmacist. Only keep it if your doctor tells you to. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist on how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Amantadine Oral Solution contain
The active substance is amantadine hydrochloride.
The other ingredients are:

- Methyl hydroxybenzoate, propyl hydroxybenzoate, sorbitol, Sodium citrate Dihydrate, strawberry flavouring and water

What Amantadine Oral Solution looks like and contents of the pack
Amantadine Oral Solution is Clear, colourless liquid with characteristic flavour. Amantadine Oral Solution comes in amber glass bottles with a tamper evident HDPE child-resistant screw cap containing 100ml or 150mL of solution.

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