

PATIENT LEAFLET: INFORMATION FOR THE USER

Amantadine hydrochloride 100 mg capsules

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 hydrochloride 100 mg capsules are and what they are used for
2. What you need to know before you take Amantadine hydrochloride 100 mg capsules
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4. Possible side effects
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1. What Amantadine hydrochloride 100 mg capsules are and what they are used for

Amantadine is an antiviral drug. Amantadine capsules are used:

To prevent or treat a certain type of flu infection (influenza A).

2. What you need to know before you take Amantadine hydrochloride 100 mg capsules

Do not take Amantadine hydrochloride 100 mg capsules:

- if you are allergic to amantadine hydrochloride or any of the ingredients of Amantadine capsules (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 capsules.

Warnings and precautions

Talk to your doctor before you take Amantadine capsules 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 capsules.

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 capsules.

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.

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

Other Medicines and Amantadine hydrochloride 100mg capsules

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

- 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.

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

Amantadine hydrochloride 100mg capsules with food and alcohol

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

Amantadine capsules should be taken with a glass of water.

Pregnancy and breast-feeding

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

Do not take Amantadine capsules if you are breast-feeding because Amantadine capsules 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 capsules 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 hydrochloride 100 mg capsules contains lactose.

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

3. How to take Amantadine hydrochloride 100 mg capsules

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.

Swallow the capsules whole with a drink of water.

The usual dose is different in the following circumstances:

Flu infections (influenza A)

Adults: 1 capsule (100 mg) a day.

Adults over 65 years: a lower dose may be appropriate for elderly patients, or as directed by the doctor/pharmacist.

Children over 10 years and adolescents: 1 capsule (100mg) a day.

Children under 10 years: as directed by your doctor.

For the prevention of flu: Amantadine capsules should be used for as long as protection is needed. Usually about 6 weeks.

For the treatment of flu: Amantadine capsules should be taken for about 4 to 5 days.

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

What to do if you take more Amantadine hydrochloride 100 mg capsules 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.

If you forget to take Amantadine hydrochloride 100 mg capsules

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 hydrochloride 100 mg capsules

If you are taking anti-psychotics (used to treat mental disturbances) and you suddenly stop taking Amantadine capsules, 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.

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 everyone 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:

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

Tell your doctor or pharmacist if you think you have any of these or other problems with Amantadine capsules.

Very common side effects (that affect more than 1 person in 10):

- swollen ankles
- red blotchy spots on the skin

Common side effects (that affect less than 1 person in 10):

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

- dry mouth

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

- blurred vision

Rare side effects (that affect less than 1 person in 1000):

- Neuroleptic Malignant Syndrome (NMS). You may feel hot and have muscle stiffness
- convulsions (fits)
- shakiness
- difficulty moving
- disorientation (not knowing where you are)
- disturbed thoughts or behaviour such as feeling paranoid
- loss of bladder control. You may have difficulty in passing water or have a sudden urge to pass water
- corneal lesion, corneal oedema, reduced visual acuity
- problems with your eyes such as itchiness or redness
- skin rash
- diarrhoea

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 hydrochloride 100 mg capsules

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.

Keep the blister in the outer carton in order to protect from moisture.

Do not throw away any medicines of 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 is in Amantadine hydrochloride 100 mg capsules?

The active substance in this medicine is amantadine hydrochloride.

Each capsule contains 100 mg of amantadine hydrochloride. The other ingredients are:

- lactose, povidone, magnesium stearate, red iron oxide (E172), titanium dioxide (E171), gelatin and monogramming ink S-1-7085 white containing: titanium dioxide (E171), ammonium hydroxide 28%, propylene glycol (E1520), simethicone or SB-0007P white ink containing: shellac, propylene glycol, sodium hydroxide, povidone, titanium dioxide (E171).

What Amantadine hydrochloride 100 mg capsules look like and contents of the pack

Amantadine capsules are a brownish-red, hard gelatin capsule with SYMM printed on them in white. Amantadine capsules comes in boxes of 5 or 14 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder: Alliance Pharmaceuticals Limited, Avonbridge House, Bath Road, Chippenham, Wiltshire, SN15 2BB, UK

Manufacturer: Chanelle Medical Unlimited Company, Dublin Road, Loughrea, Co. Galway, H62 FH90, Ireland.

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