Package leaflet: Information for the patient

Amantadine 50mg/ 5ml
Oral Solution

amantadine hydrochloride

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.

The full name of this medicine is Amantadine 50mg/5ml Oral Solution but is referred to as Amantadine Solution within this leaflet.

What is in this leaflet

1. What Amantadine solution is and what it is used for
2. What you need to know before you take Amantadine solution
3. How to take Amantadine solution
4. Possible side effects
5. How to store Amantadine solution
6. Contents of the pack and other information

1. What Amantadine solution is and what it is used for

Amantadine Solution contains the active substance amantadine. This is a dopaminergic drug, meaning that it can increase the levels of certain chemicals that transmit impulses in the nervous system, including the brain. It is also an antiviral medicine, which works against influenza A infections by stopping the virus from reproducing.

Amantadine Solution can be used:
- to treat Parkinson's disease by improving muscle control and reducing stiffness, shakiness and shuffling
- to prevent, or treat the signs and symptoms of, certain influenza ('flu) infections (type A)
- to reduce the pain caused by shingles (herpes zoster), a blistering skin rash caused by the same virus that causes chickenpox (the varicella zoster virus)

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

Do not take Amantadine Solution if:
- you are allergic to amantadine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- you have epilepsy or have ever had fits (convulsions)
- you have ever had an ulcer in your stomach or small intestine
- you suffer from any serious kidney disease
- you are pregnant or trying to become pregnant (see section 2 Pregnancy and breastfeeding)
- you are breastfeeding (see section 2 Pregnancy and breastfeeding).

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

Warnings and precautions

Talk to your doctor before taking Amantadine Solution if you:
- suffer from any liver or kidney disease
- have a history of disease involving the heart and blood vessels
- are currently suffering from heart problems or heart failure (heart problems which cause shortness of breath or ankle swelling)
- have any form of mental health problem, for example schizophrenia, dementia
- have glaucoma (increased pressure in the eye)

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

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.

Abnormally low body temperatures (below 35ºC) can occur particularly in children treated for influenza. In this case talk to your doctor straight away and stop taking Amantadine 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 Solution.

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

If you have any thoughts or feelings about harming or killing yourself tell your doctor or go to a hospital straight away. There have been reports of people taking amantadine attempting to take their own life.

Children

Do not give this medicine to children under the age of 3 years old, unless advised by your doctor or pharmacist.

There have been reports of children developing hypothermia when taking amantadine. Hypothermia is a dangerous drop in body temperature below 35°C. Early signs include cold and pale skin, shivering, slurred speech, fast breathing, tiredness, confusion. If this medicine has been prescribed for a child, and he/she shows any signs of hypothermia seek immediate medical help.

Do not stop taking Amantadine Solution suddenly without discussing it with your doctor first. Abrupt discontinuation could cause your condition to worsen or for you to have withdrawal effects which could be serious (see section 3 'If you stop taking Amantadine Solution' for further information).

Other medicines and Amantadine Solution

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because amantadine may affect the way some medicines work. Also some medicines can affect the way amantadine works.

In particular tell your doctor or pharmacist if you are taking any of the following:
- 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

Amantadine Solution with alcohol

Be careful when drinking alcohol whilst taking Amantadine Solution This is because it may affect you more than usual and can also increase the chances of you getting side effects from amantadine.

Pregnancy and breastfeeding

Do not take Amantadine Solution if you are pregnant or trying to become pregnant.
Do not take Amantadine Solution if you are breastfeeding because amantadine passes into breast milk and could harm your baby.
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Do not drive whilst taking this medicine until you know how this medicine affects you. Amantadine Solution may cause side effects that affect your ability to drive safely. For example, it may affect your vision or concentration make you feel dizzy or confused (see section 4). If this happens do not drive or use any tools or machines.

If you are in any doubt about whether it is safe for you to do a particular activity, talk to your doctor.

Amantadine Solution contains Sorbitol (E420), Sodium benzoate (E211), Ethanol, Propylene glycol (E1520) and Benzyl alcohol:

This medicine contains up to 6.5 g sorbitol in each 10 ml dose. 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 Amantadine Solution.

Sorbitol may cause gastrointestinal discomfort and a mild laxative effect

This medicine contains 20 mg sodium benzoate in each 10 ml dose.
Sodium Benzoate may increase jaundice (yellowing of the skin and eyes) in new-born babies (up to 4 weeks old).

This medicine contains less than 1mmol sodium (23mg) per 10 ml dose, that is to say essentially 'sodium-free'.

This medicine contains small amounts of ethanol (alcohol), less than 100mg per 10ml dose.

This medicine contains up to 12 mg propylene glycol in each 10 ml dose.

If this medicine has been prescribed for a baby that is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

This medicine contains 12 mg benzyl alcohol in each 10 ml dose.
Benzyl alcohol may cause allergic reactions and has been linked with the risk of severe side effects including breathing problems (called "gasping syndrome") in young children.
Do not give to your new-born baby (up to 4 weeks old), unless recommended by your doctor

Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.
Ask your doctor or pharmacist for advice if you have a liver or kidney disease or if you are pregnant or breastfeeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

3. How to take Amantadine Solution

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

The box containing this medicine contains a plastic measuring cup. The cup is marked in ml (millilitres) to help you measure out the correct amount. Take your medicine using the measuring cup and rinse it out with water after each use.

Doses

The dose of Amantadine Solution depends on what it is used for. The recommended doses are as follows, although your doctor may give you a lower dose if you have kidney problems.

For the treatment and prevention of flu:

Adults

10 ml once each day.

Adults over 65 years of age may need a lower dose or a longer time between doses.

Children

10-15 years: 10 ml once each day

Under 10 years of age: the doctor will decide the dose

If you have 'flu you should take the recommended dose for 4 to 5 days.

If you have been given Amantadine Solution for the prevention of flu it should be taken for as long as protection is needed. This is usually about 6 weeks.

This medicine should not be used in children under the age of 3 years old, unless advised by your doctor or pharmacist.

For Parkinson's Disease

Adults

The starting dose is usually 10 ml once each day for the first week or longer, which is then increased to 10 ml twice a day. Your doctor will determine the best dose for you and may gradually adjust the dose during your treatment, depending upon your response. Do not take more than 40 ml a day.

Adults over 65 years: 10ml once a day

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.

For Shingles (herpes zoster)
10 ml twice a day for 14 days.

If you are still in pain after this time your doctor may give you another 14 days treatment.

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

If you are not sure how much Amantadine Solution to take, ask your doctor or pharmacist.

If you take more Amantadine Solution than you should

If you accidentally take too much Amantadine Solution, or someone else takes any of your medicine, contact your doctor or the nearest hospital Accident and Emergency department immediately. Show the bottle to the doctor, even if it is empty.

If you forget to take Amantadine Solution

Take it as soon as you remember, unless it is almost time for your next dose. Then, take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Amantadine Solution

Do not stop taking Amantadine Solution without asking your doctor first. When stopping Amantadine Solution your doctor will tell you how to reduce your dose slowly. If you stop suddenly your symptoms may get worse and you may get withdrawal effects.

If you are taking antipsychotics (used to treat mental disturbances) and you suddenly stop taking Amantadine Solution, you may develop a medical condition called Neuroleptic Malignant Syndrome which can be serious. The symptoms include:
- fever
- sweating
- a rapid heartbeat
- muscle stiffness and loss of movement
- loss of bladder control (you may have a sudden urge to pass water).

If you develop any of these symptoms contact your doctor immediately.

If you have any further questions on the use of this product, ask your doctor or pharmacist.
Some patients may notice that this medicine loses its effect after they have taken it regularly for a few months

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

<u>If you experience any of the following serious side effects, tell your doctor immediately or go to the nearest hospital accident and emergency department</u>
- dizziness or light-headedness
- fainting
- seizures (fits).

Other possible side effects:

Very common side effects (may affect more than 1 in 10 people):
- swollen ankles
- A blotchy, reddish-blue to purple discolouration of the skin, resembling a net or lace-like pattern.

Common side effects (may affect up to 1 in 10 people):
- confusion
- loss of appetite
- anxiety
- depression
- feeling tired
- feeling overexcited
- hallucinations (seeing, hearing, feeling, smelling or tasting things that are not really there)
- difficulty in controlling movements
- feeling or being sick
- difficulty concentrating
- feeling nervous
- difficulty sleeping
- muscle pain
- headache
- nightmares
- slurred speech
- fast or irregular heartbeat
- dry mouth
- constipation
- sweating
- postural hypotension (low blood pressure, mostly when you suddenly stand up from a lying or sitting position that makes you feel dizzy or lightheaded)

Uncommon side effects (may affect up to 1 in 100 people):
- blurred vision

Rare side effects (may affect up to 1 in 1,000 people):
- disturbed thoughts or behaviour such as feeling paranoid
- fever, muscle stiffness, muscle pains, vomiting, sweating, dark urine - these may be symptoms of a serious condition known as neuroleptic malignant syndrome;
- unintentional passing of urine (leakage), not being able to empty the bladder completely
- disorientation (not knowing where you are)
- shaking
- diarrhoea
- skin rash
- problems with your eyes such as itchiness, redness and not being able to see clearly
- convulsions (fits)
- difficulty controlling movements
- corneal lesion, corneal oedema, reduced visual acuity

Very rare side effects (may affect up to 1 in 10,000 people):
- heart problems which can 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 side effects (frequency cannot be estimated from the available data):
- Quick, involuntary muscle jerk
- 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

Additional side effects in children

There have been reports of children developing hypothermia (an abnormally low body temperature, below 35ºC) but the frequency cannot be estimated from the available data:

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 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 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 carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Store in the original bottle, in order to protect from light.

Any unused oral solution should be discarded one month after first opening the bottle

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 Solution contains
- The active substance is amantadine hydrochloride. Each 5 ml contains 50 mg amantadine hydrochloride.
- The other ingredients are sodium benzoate (E211), sorbitol (E420), raspberry flavour containing ethanol, propylene glycol (E1520) and benzyl alcohol, citric acid monohydrate and purified water.

What Amantadine Solution looks like and contents of the pack

Amantadine Solution is a clear, colourless raspberry flavoured liquid, available in glass bottles containing 150ml of solution with a dosing cup.

Marketing Authorisation Holder
Northumbria Pharma Limited
Netpark, Thomas Wright Way,
Sedgefield,
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Manufacturer
Northumbria Pharma Limited
Netpark Discovery 1, William Armstrong Way
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