

**PATIENT LEAFLET: INFORMATION FOR THE USER****Amantadine hydrochloride 50 mg/5ml syrup**

**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**

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**1. What Amantadine hydrochloride 50 mg/5ml syrup is and what it is used for**

Amantadine 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 syrup is used:

- to treat Parkinson's disease by improving muscle control and reducing stiffness, shakiness and shuffling
- to prevent or treat certain flu infections (influenza A)
- in the treatment of shingles (herpes zoster), to reduce pain.

**2. What you need to know before you take Amantadine hydrochloride 50 mg/5ml syrup****Do not take Amantadine hydrochloride 50 mg/5ml syrup:**

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

**Warnings and precautions**

Talk to your doctor before you take Amantadine syrup 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 syrup.

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 syrup.

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 50 mg/5ml syrup**

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

- 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 Hydrochloride 50 mg/5ml syrup with food and alcohol**

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

### **Pregnancy and breast-feeding**

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

Do not take Amantadine syrup 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 syrup 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.

### **Important information about some of the ingredients of Amantadine Hydrochloride 50 mg/5ml syrup**

This medicine contains 3255 mg sorbitol in each 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.

This medicine contains methyl hydroxybenzoate (E 218) and propyl hydroxybenzoate (E 216) which may cause allergic reactions (possibly delayed).

This medicine contains less than 1 mmol sodium (23mg) per 5ml, that is to say essentially 'sodium-free'

### **3. How to take Amantadine hydrochloride 50 mg/5ml syrup**

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:

#### **Flu**

Adults: Two 5ml spoonfuls (100 mg) a day.

Adults over 65 years: Lower doses may be used or time between doses may be increased.

Children over 10 years and adolescents: Two 5ml spoonfuls (100mg) a day.

Children under 10 years: As directed by your doctor.

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

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

#### **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.

#### **Shingles (herpes zoster)**

The dose is four 5ml spoonfuls (200 mg) a day for 14 days. If your pain remains 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 syrup to take, ask your doctor or pharmacist.

#### **What to do if you take more Amantadine hydrochloride 50 mg/5ml syrup than you should**

If you accidentally take too much syrup, 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 hydrochloride 50 mg/5ml syrup**

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 50 mg/5ml syrup**

Do not stop taking Amantadine syrup suddenly as your symptoms may get worse.

If you want to stop taking Amantadine syrup 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 syrup, 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 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 syrup:

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](http://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 50 mg/5ml syrup**

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.

Do not store above 25°C. Keep the bottle in the outer carton in order to protect from light.

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 is in Amantadine hydrochloride 50 mg/5ml syrup**

The active substance in this medicine is amantadine hydrochloride.

The other ingredients are:

- methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), sorbitol, disodium hydrogen citrate, lemon flavour, strawberry flavour and water

### **What Amantadine hydrochloride 50 mg/5ml syrup looks like and contents of the pack**

Amantadine syrup is a clear, citrus-flavoured syrup. Amantadine syrup comes in bottles of 150ml of syrup.

## **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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## **The Parkinson's Disease Society**

The Parkinson's Disease Society is a voluntary organisation. It works to improve the quality of life of people who have Parkinson's (and their families and carers) by providing vital support and advice and funding of relevant research.

If you need independent information or advice, please contact The Parkinson's Disease Society.

Freephone helpline (9.30am to 5.30pm Monday to Friday): 0808 800 0303

Address: 215 Vauxhall Bridge Road, London SW1V 1EJ

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