PATIENT INFORMATION LEAFLET

Amantadine hydrochloride 50 mg/5ml syrup

Read all of this leaflet carefully before you start taking this medicine

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any effects not listed in this leaflet please tell your doctor or pharmacist.

The information in this leaflet has been divided into the following sections:

1. What Amantadine hydrochloride 50 mg/5ml syrup is and what it is taken for
2. Check before you take Amantadine hydrochloride 50 mg/5ml syrup
3. How to take Amantadine hydrochloride 50 mg/5ml syrup
4. Possible side effects
5. How to store Amantadine hydrochloride 50 mg/5ml syrup
6. Further information

1. What Amantadine hydrochloride 50 mg/5ml syrup is and what it is taken 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, shaking and shuffling
- to prevent or treat certain flu infections (influenza A)
- in the treatment of shingles (herpes zoster), to reduce pain.

2. Check before you take Amantadine hydrochloride 50 mg/5ml syrup

Do not take Amantadine hydrochloride 50 mg/5ml syrup:
- if you are allergic (hypersensitive) to amantadine hydrochloride or any of the ingredients of Amantadine syrup (see Section 6 Further information)
- if you suffer from flu (consequences), for example: may be more a precaution
- 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.

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

Before you take Amantadine syrup tell your doctor:
- 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 35ºC) can occur particularly in children treated for influenza. In this case talk to your doctor straight away and stop taking Amantadine syrup.

Taking other medicines
Tell your doctor or pharmacist if you are taking or have recently taken 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 allergies) 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, amiodarone 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 and drink
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

Amantadine syrup contains methyl hydroxybenzoate (E218) and propyl hydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

Please read all of this leaflet carefully before you start taking this medicine 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.
Children (10 to 15 years): Two 5ml spoonfuls (50mg) 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.

Children (under 10 years): As directed by your doctor.

Shingles (herpes zoster)
This 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.

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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. Store any left-over medicine in a safe place out of the reach of children.

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.

If you stop taking Amantadine hydrochloride 50 mg/5ml syrup

If you stop taking Amantadine syrup suddenly as your symptoms may get worse.

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, Amantadine syrup 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:

• dizziness or lightheadedness
• fainting
• dizziness or lightheadedness
• feeling or being sick
• blurred vision
• muscle stiffness (difficulty in movement)
• eczema
• loss of bladder control (you may have a sudden urge to pass water).
• convulsions (fits).
• sweating
• fever
• unusual tiredness
• dry mouth
• constipation

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

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

• hallucinations
• depression
• anxiety
• loss of appetite
• nausea
• sensitivity to sunlight.

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

• heart problems which cause shortness of breath or ankle swelling
• problems with your eyes such as itchiness or redness.

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).

By reporting side effects, you can help provide more

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). By reporting side effects, you can help provide more

Abnormally low body temperature (below 35ºC) 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.

5. How to store Amantadine hydrochloride 50 mg/5ml syrup

Keep out of the reach and sight of children.

Do not use Amantadine syrup 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 25ºC. Keep the bottle in the outer carton in order to protect from light.

If you stop taking Amantadine syrup ask your doctor or pharmacist what you should do when you complete the course of treatment.

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

If your doctor decides to stop your treatment, return any unused medicine to the pharmacist. Only keep it if your doctor tells you to.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist on how to dispose of medicines no longer

5. Further information

What is in Amantadine hydrochloride 50 mg/5ml syrup

The active ingredient 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

The product licence holder is: TEVA UK Limited, Eastbourne, BN22 9AG, UK

Amantadine syrup is manufactured by: Chanelle Medical, Loughrea, Co. Galway, Ireland.

The information in this leaflet applies only to Amantadine syrup. If you have any questions or you are not sure about anything, ask your doctor or pharmacist.

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.

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