Package leaflet: Information for the patient

Amantadine Hydrochloride 100 mg Hard Capsules

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.
- In this leaflet Amantadine Hydrochloride 100 mg Hard Capsules will be called Amantadine Capsules.

What is in this leaflet

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

1. What Amantadine Capsules are and what they are 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 is also an antiviral drug.

Amantadine Capsules are used:
- to treat Parkinson's disease by improving muscle control and reducing stiffness, shakiness and shuffling
- in the treatment of shingles (herpes zoster), to reduce pain
- to prevent or treat a certain type of flu infection (influenza A).

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

Do not take Amantadine Capsules
- if you are allergic to amantadine hydrochloride or any of the other ingredients of this medicine (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)
- if you are breast-feeding (see section 2)

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 or pharmacist before taking 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.

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.

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 Capsules.

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

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

Other medicines and Amantadine Capsules
Tell your doctor or pharmacist if you are taking or have recently taken, or might take 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.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Amantadine 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, breast-feeding and fertility
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 passes into breast milk and could harm your baby.

If you are pregnant or breast-feeding, 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
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 Capsules contains lactose
If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

3. How to take Amantadine Capsules

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

Parkinson's disease
Adults: 1 capsule (100 mg) a day for the first week. Your doctor will increase this to 2 capsules a day (200 mg). Higher doses, up to 4 capsules (400 mg) a day may be given in some cases.

Adults over 65 years: 1 capsule (100 mg) once a day.

Shingles (herpes zoster)
The dose is 2 capsules (200 mg) a day for 14 days. If your pain continues your doctor may give you another 14 days treatment.

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 (100 mg) once 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. This is usually about 6 weeks.

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

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

If you take more Amantadine 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 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 Capsules
Do not stop taking Amantadine Capsules suddenly as your symptoms may get worse.

If you want to stop taking Amantadine Capsules 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 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.

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 Capsules:

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):
- 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.
- dry mouth
- loss of appetite
- feeling or being sick
- constipation
- sweating
- muscle pain

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

Very rare side effects (may affect up to 1 in 10,000 people):
- reduction in the number of white blood cells which makes infections more likely
- heart problems which cause shortness of breath or ankle swelling
- sensitivity to sunlight
- changes in blood tests which show how the liver is working

Not known (frequency cannot be estimated from the available data):
- urge to behave in an unusual way, for example
  - 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 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 label and carton (EXP). The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Capsules contains
- The active substance is amantadine hydrochloride. Each capsule contains 100 mg amantadine hydrochloride, equivalent to 80.6 mg of amantadine.
- The other ingredients are lactose monohydrate, povidone and magnesium stearate (E572). The capsule shells consist of gelatin and titanium dioxide (E171).

What Amantadine Capsules looks like and contents of the pack
Amantadine Capsules are opaque, white, hard gelatin capsules, packed in blisters, available in packs of 28 or 56 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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This leaflet was last revised in November 2024.

NEON
HEALTHCARE

Artwork Specifictaion

Template No.:	RA_L_009
Dimensions:	135 x 550 mm
Text Colour:	Black
Font:	Times New Roman
Minimum Font Size:	8.7pt
Version:	6
Date:	02 December 2024