

PACKAGE LEAFLET: INFORMATION FOR THE USER

MORNINGSIDE

HEALTHCARE

Amantadine Hydrochloride

100mg 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 Capsules are and what they are used for
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4. Possible side effects
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1. What Amantadine Capsules are and what they are used for

The name of your medicine is Amantadine Hydrochloride 100mg Capsules (called Amantadine Capsules in the rest of this leaflet).

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 hydrochloride 100mg 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),
- you suffer from fits (convulsions), for example epilepsy,
- 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 'Pregnancy and breast-feeding'),
- you are breast-feeding (see Section 'Pregnancy and breast-feeding').

Do not take Amantadine Capsules if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking 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 you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking 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.

Other medicines and Amantadine Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription and herbal medicines. This is because Amantadine Capsules can affect the way some other medicines work and some medicines can have an effect on Amantadine Capsules.

In particular, tell your doctor if you are taking any of the following medicines:

- 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.

Amantadine Capsules with food, drink 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.

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 Capsules contain lactose

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

3. How to take Amantadine Capsules

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

Swallow the capsules whole with a drink of water.

The recommended dose is different in the following circumstances:

Parkinson's disease:

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

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

Shingles (herpes zoster):

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

Flu infections (influenza A):

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|-----------------------|--|
| Adults: | 1 capsule (100 mg) a day. |
| Adults over 65 years: | 1 capsule (100 mg) a day. |
| Children: | (10 to 15 years): 1 capsule (100mg) a day. |

as directed by your doctor.

Children (under 10 years):

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.

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

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose. 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 medicine, 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 (may affect more than 1 in 10 people)

- swollen ankles,
- red blotchy spots on the skin.

Common (may affect up to 1 in 10 people)

- anxiety,
- feeling overexcited,
- headache,
- feeling tired,
- hallucinations,
- nightmares,
- difficulty in controlling movements,
- slurred speech,
- blurred vision,
- difficulty concentrating,
- feeling nervous,
- depression,
- difficulty sleeping,
- muscle pain,
- 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.

Rare (may affect up to 1 in 1,000 people)

- confusion,
- disorientation (not knowing where you are),
- disturbed thoughts or behaviour such as feeling paranoid,
- shakiness,
- difficulty moving,
- neuroleptic malignant syndrome (NMS). You may feel hot and have muscle stiffness,
- diarrhoea,
- skin rash,
- problems with your eyes such as itchiness or redness,
- loss of bladder control. You may have difficulty in passing water or have a sudden urge to pass water.

Very rare (may affect up to 1 in 10,000 people)

- 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.

Abnormally low body temperature (below 35°C) has been observed especially in children.

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 at 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.

6. Contents of the pack and other information

What Amantadine Capsules contain

The active substance is amantadine hydrochloride. Each hard gelatin capsule contains 100 mg amantadine hydrochloride.

The other ingredients are:

- Capsule filling containing lactose monohydrate, povidone and magnesium stearate.
- Capsule shell containing gelatin, titanium dioxide (E171), sodium laurilsulfate and iron oxide red (E172).
- Printing Ink - White containing shellac (E904), titanium dioxide (E171) and propylene glycol (E1520).

What Amantadine Capsules look like and contents of the pack

Amantadine Hydrochloride 100mg Capsules are brownish-red, size 3, hard gelatin capsule imprinted AM100 in white on both cap and body.

The capsules are packaged in PVC/PVdC-Alu blister packs. Pack size of 5, 7, 10, 14, 28, 30 and 56 capsules are available.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Morningside Healthcare Ltd.

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Manufacturer

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This leaflet was last revised in September 2018.

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

Do not store above 25°C.

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.