

Package leaflet: Information for the patient

Trilasym 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 Trilasym 50mg/5ml Oral Solution but is referred to as Trilasym Solution within this leaflet.

What is in this leaflet

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

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

Trilasym 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.

Trilasym 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 Trilasym Solution

Do not take Trilasym 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 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 Trilasym Solution.

Warnings and precautions

Talk to your doctor before taking Trilasym 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 problems thinking clearly or quickly, feel disorientated; find it difficult to pay attention, make decisions or remember things
- sometimes see, hear, feel, smell or taste things that are not really there (have hallucinations)
- 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 Trilasym 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 Trilasym 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.

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 Trilasym 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 Trilasym Solution' for further information).

Other medicines and Trilasym 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:

- Medicines called **anti-muscarinics** or **anti-cholinergics**, which affect the way nerve cells function in order to treat certain medical conditions. They include medicines used for Parkinson's Disease e.g. procyclidine, orphenadrine; irritable bowel syndrome and diverticular disease e.g. dicycloverine, hyoscine, propantheline; asthma and chronic obstructive pulmonary disease (COPD) e.g. ipratropium, tiotropium; incontinence e.g. oxybutynin, tolterodine, flavoxate
- **levodopa**, used to treat Parkinson's disease
- medicines called **anti-psychotics**, used to help people feel calmer and improve thoughts, feelings and behaviour when disturbed due to conditions such as schizophrenia, mania, delirium. Examples of anti-psychotic medicines include chlorpromazine, flupenthixol, zuclopenthixol, haloperidol, quetiapine, risperidone
- medicines called **diuretics** (water tablets), used to relieve water retention and reduce high blood pressure e.g. medicines containing hydrochlorothiazide and amiloride or triamterene.

Trilasym Solution with alcohol

Be careful when drinking alcohol whilst taking Trilasym 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 breast-feeding

Do not take Trilasym Solution if you are pregnant or trying to become pregnant.

Do not take Trilasym Solution 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

Do not drive whilst taking this medicine until you know how this medicine affects you. Trilasym 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.

Trilasym 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 Trilasym Solution.

Sorbitol may cause gastrointestinal discomfort and 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 "gaspings 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 breast-feeding. 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 Trilasym 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 Trilasym 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 Trilasym 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.

For Parkinson's Disease

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.

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 Trilasym Solution to take, ask your doctor or pharmacist.

If you take more Trilasym Solution than you should

If you accidentally take too much Trilasym 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 Trilasym 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 Trilasym Solution

Do not stop taking Trilasym Solution without asking your doctor first. When stopping Trilasym 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. Withdrawal effects may include feelings of being dazed, confused, restless, distracted, withdrawn, weak, sleepy; being unable to speak, doing unusual things and seeing things that are not really there.

If you are taking anti-psychotics (used to treat mental disturbances) and you suddenly stop taking Trilasym Solution, you may develop a medical condition called Neuroleptic Malignant Syndrome which can be serious. The symptoms include:

- fever
- sweating
- a rapid heart beat
- muscle stiffness and loss of movement - confusion

- 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.

4. Possible side effects

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

If you experience any of the following serious side effects, tell your doctor immediately or go to the nearest hospital accident and emergency department

- 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):

- 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
- blurred vision
- feeling or being sick
- difficulty concentrating
- feeling nervous
- difficulty sleeping
- muscle pain
- headache
- nightmares
- slurred speech
- feeling your 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):

- confusion
- 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
- unusual uncontrollable 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
- a red, itchy or burning skin rash on areas of skin exposed to sunlight

Not known side effects (frequency cannot be estimated from the available data):

- restlessness, having illusions and not making sense; a condition known as delirium
- decreased need for sleep, with heightened mood (either euphoric or irritable), feel extremely outgoing, with a great deal of energy more than normal; a condition which depending on its extent is known as hypomanic state or mania.
- Urge to behave in an usual 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 35°C) 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 Trilasym 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 Trilasym 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 Trilasym Solution looks like and contents of the pack

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

Marketing Authorisation Holder and Manufacturer Marketing Authorisation Holder

Fontus Health Ltd

60 Lichfield Street

Walsall

WS4 2BX

United Kingdom

Manufacturer

Northumbria Pharma Ltd
Netpark, Thomas Wright Way,
Sedgefield,
County Durham TS21 3FD
United Kingdom and
Purna Pharmaceuticals NV
Rijksweg 17, Puurs, 2870.
Belgium.

This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom - Trilasym 50mg/ 5ml Oral Solution

Malta - Trilasym 50mg/ 5ml Oral Solution

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