

Galantamine 4mg/ml Oral Solution

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

1. What Galantamine Oral Solution is and what it is used for

What your medicine is

The full name of your medicine is Galantamine 4mg/ml Oral Solution. In this leaflet the shorter name Galantamine is used. Galantamine belongs to a group of medicines known as 'anti-dementia' medicines.

What your medicine is used for

Galantamine is used in adults to treat the symptoms of mild to moderately severe Alzheimer's disease. This is a type of dementia that alters the way the brain works. Alzheimer's disease causes memory loss, confusion and changes in behaviour, which make it increasingly difficult to carry out normal daily tasks.

How your medicine works

The effects of Alzheimer's disease on the brain are thought to be caused by a lack of 'acetylcholine'. This is a substance which sends messages between brain cells. Galantamine increases the amount of 'acetylcholine' in the brain and helps more messages be sent.

2. What you need to know before you take Galantamine Oral Solution

Do not take Galantamine:

- if you are allergic (hypersensitive) to galantamine or any of the other ingredients of this medicine (listed in section 6)
- if you have a severe liver or kidney problem.

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

Serious side effects

Galantamine can cause some side effects where you need to stop taking your medicine and tell your doctor straight away. These include heart problems and fits (seizures). See 'Serious side effects' at the top of section 4.

Warnings and precautions

Talk to your doctor or pharmacist before taking Galantamine. This medicine is only used for Alzheimer's disease and is not recommended for other types of memory loss or confusion.

Before you take Galantamine, your doctor needs to know if you have, or have had, any of the following:

- liver or kidney problems
- a heart condition (such as chest discomfort that is often brought on by physical activity, a heart attack, heart failure, slow or uneven heartbeat, prolonged QTc interval)
- changes in levels of naturally occurring chemicals in the blood called 'electrolytes' such as potassium
- stomach ulcers
- blockage in your stomach or intestines
- a problem with your nervous system (such as epilepsy or Parkinson's disease)
- an infection or problem which affects your breathing (such as asthma, obstructive pulmonary disease or pneumonia)
- problems passing urine.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Galantamine.

Operations or tests

Tell your doctor if you have recently had an operation on your stomach, intestines or bladder. Your doctor may decide that Galantamine is not suitable for you.

Galantamine may affect some medicines used during an operation ('anaesthetics'). If you are going to have an operation, tell your doctor that you are taking Galantamine well in advance.

Galantamine and your weight

Your doctor will check your weight regularly when you take Galantamine. This is because Galantamine can cause weight loss.

Children and adolescents

Galantamine is not recommended for children or adolescents.

Other medicines and Galantamine

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 Galantamine can affect the way some other medicines work. Also, some other medicines can affect the way Galantamine works.

Galantamine should not be used with medicines that work in a similar way. These include:

- other medicines for Alzheimer's disease called donepezil or rivastigmine
- medicines for severe muscle weakness called ambenonium, neostigmine or pyridostigmine
- a medicine for dry mouth or eyes called pilocarpine (when taken by mouth).

Do not take Galantamine with any of the medicines above that work in a similar way.

Tell your doctor if you are taking any of the following medicines. They can make side effects more likely so your doctor may give you a lower dose of Galantamine. These include:

- medicines affecting the QTc interval
- medicines for pain and inflammation called non-steroidal anti-inflammatories or NSAIDs such as ibuprofen (these can increase the risk of ulcers)
- medicines for heart problems or high blood pressure such as digoxin, amiodarone, atropine, beta-blockers, or calcium channel blocking agents (your doctor may check your heart using an electrocardiogram or ECG)
- medicines for depression called paroxetine or fluoxetine
- a medicine for an uneven heartbeat called quinidine
- a medicine for fungal infections called ketoconazole
- an antibiotic called erythromycin
- a medicine for HIV called ritonavir.

Tell your doctor if you are taking any of the medicines listed above. They can make side effects more likely so your doctor may give you a lower dose of Galantamine. If you have any questions, talk to your doctor or pharmacist for advice.

Pregnancy and breast-feeding

- If you are pregnant, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
- Do not breast-feed while you are taking Galantamine.

Driving and using machines

You may feel dizzy or sleepy while taking Galantamine, especially during the first few weeks of treatment. If this happens, do not drive, cycle, use any tools or machines.

Galantamine Oral Solution contains sodium methyl, sodium propyl parahydroxybenzoates, and sodium saccharin

- Sodium methyl and sodium propyl parahydroxybenzoates may cause an allergic reaction which may happen some time after starting the medicine.
- This medicine contains less than 1 mmol sodium (23 mg) per ml that is to say essentially 'sodium-free'.

3. How to take Galantamine Oral Solution

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

How much to take

- You will start on a low dose.
- The usual starting dose is 4mg (1ml of solution) taken twice a day. This is a total of 8mg a day.
- Your doctor may gradually increase your dose every 4 weeks or more until you reach a dose that is suitable for you.
- The maximum dose is 12mg (3ml of solution) taken twice a day. This is a total of 24mg a day.
- Your doctor will explain what dose to start with and when the dose should be increased.
- If you are not sure what to do or you find the effect of Galantamine is too strong or weak, talk to your doctor or pharmacist.

Your doctor will need to see you regularly, to check the medicine is working and to discuss how you are feeling.

People with liver or kidney problems

Your doctor may give you a lower dose of Galantamine, or they may decide this medicine is not suitable for you.

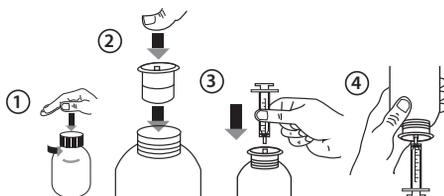
Taking this medicine

- You need to take your dose twice a day, in the morning and evening, with water.
- Try to take Galantamine with food.
- Drink plenty of liquids during the day, to keep hydrated.

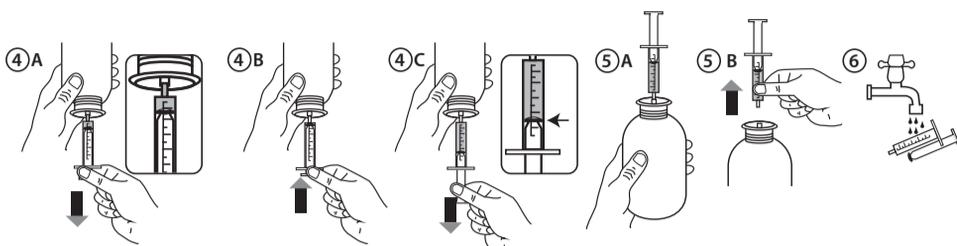
Measuring your dose

The solution comes with a syringe. This should be used to measure the exact amount of medicine you need.

- Open the bottle by pressing the cap and turning it anticlockwise (Figure 1).
- Insert the syringe adaptor into the bottle neck (Figure 2).
- Take the syringe and put it in the adaptor opening (Figure 3).
- Turn the bottle upside down (Figure 4).



- Fill the syringe with a small amount of solution by pulling the piston down (Figure 4A). Then push the piston upward in order to remove any possible bubbles (Figure 4B). Finally, pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (Figure 4C).
- Turn the bottle the right way up (Figure 5A).
- Remove the syringe from the adaptor (Figure 5B). Empty the syringe into any non-alcoholic drink and use immediately.
- Wash the syringe with water and let it dry before you use it again (Figure 6).
- Close the bottle with the plastic screw cap - leave the syringe adaptor in the bottle.



If you take more Galantamine than you should

If you take too much Galantamine, contact a doctor or go to hospital straight away. Take any remaining solution and the packaging with you. The signs of an overdose may include:

- severe nausea and vomiting
- weak muscles
- slow heartbeat
- fits (seizures) or loss of consciousness.

If you forget to take Galantamine

- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual. If you miss two or more doses, contact your doctor.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking Galantamine

Do not stop taking this medicine without talking to your doctor. Your signs may return. It is important to continue taking this medicine to treat your condition.

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.

Serious side effects

Stop taking Galantamine and tell your doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- **heart problems** – including changes in your heartbeat such as a slow heartbeat, extra beats or your heartbeat feeling is fast or uneven. These may show as an abnormal tracing on an electrocardiogram (ECG). They are common and may affect up to 1 in 10 people
- **fits (seizures)** – these are uncommon and may affect up to 1 in 100 people.
- **skin reactions, including:**
 - severe rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome),
 - red rash covered with small pus-filled bumps that can spread over the body, sometimes with a fever (acute generalized exanthematous pustulosis).
 - rash that may blister, with spots that look like small targets.

These skin reactions are rare in people taking Galantamine (may affect up to 1 in 1,000 people).

Stop taking Galantamine and tell your doctor straight away if you notice any of the serious side effects above – you may need urgent medical treatment.

Other side effects

Tell your doctor or pharmacist if you notice any of the following side effects:

Very common side effects (may affect more than 1 in 10 people)

- feeling or being sick. These are more likely to happen in the first few weeks of treatment or when the dose is increased. They tend to disappear gradually as your body gets used to the medicine and generally only last for a few days. If you have these effects, your doctor may recommend that you drink more liquids and may give you a medicine to stop you being sick.

Common side effects (may affect up to 1 in 10 people)

- decreased appetite, weight loss
- seeing, feeling or hearing things that are not there (hallucinations)
- depression
- feeling dizzy or fainting
- muscle tremors or spasms
- headache
- feeling very tired, sleepy, weak, like you have low energy or are generally unwell
- high blood pressure
- stomach pain or discomfort, indigestion, diarrhoea
- being more likely to fall or injure yourself (wounds).

Uncommon side effects (may affect up to 1 in 100 people)

- allergic reaction
- not enough water in the body (dehydration)
- tingling or numb feeling of the skin (pins and needles)
- change in sense of taste
- feeling sleepy during the day
- blurred vision
- ringing in the ear that does not go away (tinnitus)
- low blood pressure
- flushing or excessive sweating
- feeling the need to vomit (retch)
- weak muscles
- increased levels of enzymes (shown in blood tests).

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

- inflammation of the liver (hepatitis).

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.

5. How to store Galantamine Oral Solution

- Keep this medicine out of the sight and reach of children.
- Store in the original bottle in order to protect from light. Do not freeze.
- Only use for up to 3 months after first opening. After 3 months, take it back to the pharmacy.
- Do not use this medicine after the expiry date (month, year) which is stated on the label after "EXP". The expiry date refers to the last day of that month.
- 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 to protect the environment.

6. Contents of the pack and other information

What Galantamine contains

- The active substance is galantamine hydrobromide. Each 1ml of oral solution contains 4mg of galantamine.
- The other ingredients are sodium saccharin, sodium propyl parahydroxybenzoate (E217), sodium methyl parahydroxybenzoate (E219), dilute hydrochloric acid and purified water.

What Galantamine looks like and contents of the pack

Galantamine is a clear colourless solution. It comes in a brown glass bottle holding 100ml of solution with a 3ml syringe and bottle adaptor.

The Marketing Authorisation Holder and Manufacturer is

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.
Tel: + 44 (0) 113 244 1400

This leaflet was last revised in 02/2021.

Other sources of information

This leaflet is also available in other formats for blind and partially-sighted patients. For large print and Braille, please go to www.xpil.medicines.org.uk

For an audio version, please go to www.rosemontpharma.com/products