

## Package leaflet: Information for the user

# Galzemic 4 mg/ml Oral Solution

galantamine

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

## 1. What Galzemic Oral Solution is and what it is used for

Galzemic Oral Solution contains the active substance 'galantamine', an antimentia medicine. It is used in adults to treat the symptoms of mild to moderately severe Alzheimer's disease, a type of dementia that alters brain function.

Alzheimer's disease causes increasing memory loss, confusion and behavioural changes, which make it increasingly difficult to carry out normal daily activities. These effects are thought to be caused by a lack of 'acetylcholine', a substance responsible for sending messages between brain cells. Galzemic Oral Solution increases the amount of acetylcholine in the brain and treats the signs of the disease.

## 2. What you need to know before you take Galzemic Oral Solution

### Do not take Galzemic Oral Solution

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

### Warnings and precautions

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

### Serious side effects

Galzemic Oral Solution can cause heart problems and fits (seizures). You must be aware of these side effects while you are taking this medicine. See 'Look out for serious side effects' in section 4.

Tell your doctor if you have, or have had, any of the following **before you take** this medicine:

- 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 heart beat, prolonged QTc interval),
- changes in 'electrolyte' levels (naturally occurring chemicals in the blood, such as potassium),
- a peptic (stomach) ulcer,
- blockage of the stomach or intestines,
- a disorder of the nervous system (such as epilepsy or Parkinson's disease),
- a respiratory disease or infection that affects breathing (such as asthma, obstructive pulmonary disease or pneumonia),
- problems passing urine.

Your doctor will decide if Galzemic Oral Solution is suitable for you, or if the dose needs to be changed.

**Also tell your doctor if you recently had an operation** on the stomach, intestines or bladder. Your doctor may decide that Galzemic Oral Solution is not suitable for you.

**Galzemic Oral Solution can cause weight loss.** Your doctor will check your weight regularly while you are taking this medicine.

### Children and adolescents

Galzemic Oral Solution is not recommended for children and adolescents.

### Other medicines and Galzemic Oral Solution

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

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

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

Some medicines can make side effects more likely in people taking Galzemic Oral Solution. These include:

- paroxetine or fluoxetine (antidepressants),
- quinidine (for uneven heart beat),
- ketoconazole (an antifungal),
- erythromycin (an antibiotic),
- ritonavir (for human immunodeficiency virus or 'HIV'),
- non-steroidal anti-inflammatory painkillers (such as ibuprofen), which can increase the risk of ulcers,
- medicines taken for heart conditions or high blood pressure (such as digoxin, amiodarone, atropine, beta-blockers, or calcium channel blocking agents). If you take medicines for an uneven heart beat, your doctor may check your heart using an 'electrocardiogram' (ECG),
- medicines affecting the QTc interval.

Your doctor may give you a lower dose of Galzemic Oral Solution if you are taking some of these medicines.

Galzemic Oral Solution may affect some anaesthetics. If you are going to have an operation under a general anaesthetic, tell the doctor that you are taking this medicine, well in advance.

If you have any questions, talk to your doctor or pharmacist for advice.

### Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

**You should not breast-feed while you are taking Galzemic Oral Solution.**

### Driving and using machines

Galzemic Oral Solution may make you feel dizzy or sleepy, especially during the first few weeks of treatment. If this medicine affects you, do not drive or use any tools or machinery.

### Galzemic Oral Solution contains methyl and propyl parahydroxybenzoates

These ingredients can sometimes cause allergic reactions, which may possibly be delayed.

## 3. How to take Galzemic 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 treatment with Galzemic Oral Solution at a low dose. The usual starting dose is 4 mg (1 ml of solution), taken twice a day (a total of 8 mg 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 12 mg (3 ml of solution), taken twice a day (a total of 24 mg 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 find the effect of Galzemic Oral Solution is too strong or too weak, talk to your doctor or pharmacist.

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

**If you have liver or kidney problems,** your doctor may give you a reduced dose of Galzemic Oral Solution, or may decide this medicine is not suitable for you.

### How to take

Take your dose of Galzemic Oral Solution twice a day, in the morning and evening, with water or other liquids. Try to take this medicine with food.

Drink plenty of liquids while you are taking this medicine, to keep yourself hydrated.

The solution comes with a syringe which you should use to take the exact amount needed from the bottle.

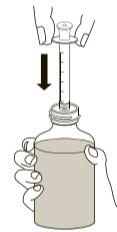
The oral syringe has a maximum volume of 5 ml.

### Directions for opening the bottle and using the pipette

1. Remove the cap.

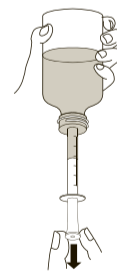


2. While the bottle is upright, on a flat surface, insert the oral syringe into the bottle.



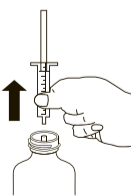
3. Turn the bottle upside down while holding the oral dosing syringe in place. Slowly pull back the plunger of the oral dosing syringe to the graduation mark that marks the dose for you.

To measure the dose accurately, the top edge of the plunger should be lined up with the appropriate graduated mark on the oral dosing syringe



- If large bubbles can be seen, slowly push the plunger back into the syringe. This will force the medicine back into the bottle. Repeat step 3 again.

4. Turn the bottle back upright with the oral dosing syringe still in place. Remove the oral dosing syringe from the bottle

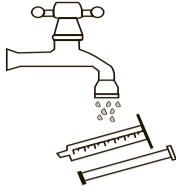


5. Empty the oral syringe into any non-alcoholic drink by sliding the upper ring down and drink it immediately



6. Close the bottle.

7. Rinse the oral syringe with some water.



#### **If you take more Galzemic Oral Solution than you should**

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

- severe nausea and vomiting,
- weak muscles, slow heart beat, fits (seizures) and loss of consciousness.

#### **If you forget to take Galzemic Oral Solution**

If you forget to take one dose, miss out the forgotten dose completely and take the next dose at the normal time. **Do not take a double dose to make up for a forgotten dose.**

If you forget to take more than one dose, contact your doctor.

#### **If you stop taking Galzemic Oral Solution**

Check with your doctor before you stop taking Galzemic Oral Solution. 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.

#### **Look out for serious side effects**

**Stop taking Galzemic Oral Solution and see a doctor immediately** if you notice any of the following:

##### **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 Galzemic Oral Solution (may affect up to 1 in 1,000 people).

**Heart problems** including changes in heart beat (such as a slow beat, extra beats), palpitations (heart beat feels fast or uneven), breathlessness or chest pain.

Heart problems may show as an abnormal tracing on an 'electrocardiogram' (ECG), and can be common in people taking Galzemic Oral Solution (may affect up to 1 in 10 people).

**Fits (seizures).** These are uncommon in people taking Galzemic Oral Solution (may affect up to 1 in 100 people).

You must stop taking Galzemic Oral Solution and get help immediately **if you notice any of the side effects above.**

#### **Other side effects**

**Very common** (may affect more than 1 in 10 people):

- nausea and vomiting. These side effects are more likely to happen in the first few weeks of treatment or when the dose is increased. They tend to disappear gradually as the 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 prescribe a medicine to stop you being sick.

**Common** (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, weak or generally unwell,
- feeling very sleepy with low energy,
- high blood pressure,
- stomach pain or discomfort,
- diarrhoea,
- indigestion,
- falls,
- 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,
- daytime sleepiness,
- blurred vision,
- ringing in the ears that does not go away (tinnitus),
- low blood pressure,
- flushing,
- feeling the need to vomit (retch),
- excessive sweating,
- weak muscles,
- increased level of liver enzymes in the blood.

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

- inflamed 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](http://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 Galzemic Oral 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 label after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not freeze.

Galzemic Oral Solution should be used within 3 months of first opening. A new bottle should be used if required.

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 Galzemic Oral Solution contains**

The active substance is galantamine. 1 ml of Galzemic Oral Solution contains 4 mg of galantamine (as hydrobromide).

The other ingredients are:

- methyl parahydroxybenzoate (E218),
- propyl parahydroxybenzoate (E216),
- purified water,
- strawberry flavour
- sodium hydroxide.

#### **What Galzemic Oral Solution looks like and contents of the pack**

Galzemic Oral Solution is a clear colourless oral solution that comes in a bottle. The oral solution is packaged in a 100 ml amber polyethylene terephthalate bottle closed with a press-in bottle adapter and with a pilfer proof aluminium cap with an expanded polyethylene/polyethylene liner. The bottle is packed in a cardboard box, which also contains the package leaflet.

The product pack contains one 100 ml bottle of medicine (with adapter) and one oral syringe. The oral syringe is marked for doses of 1 and 3 ml.

#### **Marketing Authorisation Holder and Manufacturer**

##### **Marketing Authorisation Holder**

Zentiva Pharma UK Limited  
12 New Fetter Lane  
London  
EC4A 1JP  
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##### **Manufacturer**

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6 – 28760 Tres Cantos – Madrid (ESPAÑA)

**This leaflet was last revised in September 2021**