

PACKAGE LEAFLET: INFORMATION FOR THE USER

**Galzemic XL 8 mg
prolonged-release capsules
Galzemic XL 16 mg
prolonged-release capsules
Galzemic XL 24 mg
prolonged-release capsules**

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

1. What Galzemic XL is and what it is used for

Galzemic XL contains the active substance ‘galantamine’, an antidementia 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 XL increases the amount of acetylcholine in the brain and treats the signs of the disease.

The capsules are made in a ‘prolonged-release’ form. This means that they release the medicine slowly

2. What you need to know before you take Galzemic XL

Do not take Galzemic XL if you:

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Galzemic XL.

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 XL can cause serious skin reactions, heart problems and fits (seizures). You must be aware of these side effects while you are taking Galzemic XL. See ‘Look out for serious side effects’ in section 4.

Before you take Galzemic XL, 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 ‘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 problems controlling movements of the body or limbs (extrapyramidal disorder)]
- 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 XL 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 XL is not suitable for you.

Galzemic XL can cause weight loss. Your doctor will check your weight regularly while you are taking Galzemic XL.

Children and adolescents

Galzemic is not recommended for children and adolescents.

Other medicines and Galzemic XL

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

Galzemic XL must 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 XL. These include:

- medicines affecting the QTc interval.
- 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 heartbeat, your doctor may check your heart using an electrocardiogram (ECG)

Your doctor may give you a lower dose of Galzemic XL if you are also taking any of these medicines.

Galzemic XL may affect some anaesthetics. If you are going to have an operation under a general anaesthetic, tell the doctor that you are taking Galzemic XL, 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 breastfeed while you are taking Galzemic XL.

Driving and using machines

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

3. How to take Galzemic XL

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

If you are currently taking galantamine tablets or oral solution and have been told by your doctor to switch to Galzemic XL prolonged-release capsules, carefully read the instructions under ‘Switching from taking galantamine tablets or oral solution to galantamine capsules’ in this section.

How much Galzemic XL to take

You will start treatment with Galzemic XL at a low dose. The recommended starting dose is 8 mg galantamine, taken once 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 24 mg galantamine, taken once 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 XL 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 a liver or kidney problem, your doctor may give you a reduced dose of Galzemic XL or may decide this medicine is not suitable for you.

Switching from taking galantamine tablets or oral solution to galantamine capsules

If you are currently taking galantamine tablets or oral solution, your doctor may decide you should switch to Galzemic XL prolonged-release capsules. If this applies to you:

- Take your last dose of galantamine tablets or oral solution in the evening
- The next morning, take your first dose of Galzemic XL prolonged-release capsule.

DO NOT take more than one capsule in a day. While you are taking once daily Galzemic XL capsules, DO NOT take galantamine tablets or oral solution.

How to take Galzemic XL

Galzemic XL is for oral use.

The capsules must be swallowed whole and NOT chewed or crushed.

Take your dose of Galzemic XL once a day in the morning, with water or other liquids. Try to take Galzemic XL with food.

Drink plenty of liquids while you are taking Galzemic XL, to keep yourself hydrated.

If you take more Galzemic XL than you should

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

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

If you forget to take Galzemic XL

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 XL

Check with your doctor before you stop taking Galzemic XL. 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 this medicine and see a doctor or go to your nearest emergency department 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 XL (may affect up to 1 in 1,000 people).

- **Heart problems** including changes in heartbeat (such as a slow beat, extra beats), palpitations (heartbeat feels fast or uneven). Heart problems may show as an abnormal tracing on an electrocardiogram (ECG) and can be common in people taking Galzemic XL (may affect up to 1 in 10 people).
- **Fits (seizures)**. These are uncommon in people taking Galzemic XL (may affect up to 1 in 100 people).

You must stop taking Galzemic XL and seek help immediately if you notice any of the side effects listed above.

Other side effects:

Very common side effects (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 medicines 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 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, 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
- Problems controlling movements of the body or limbs (extrapyramidal disorder).
- 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 or search for the 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 XL

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 carton, bottle and blister after “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 Galzemic XL contains

- The active substance is galantamine. Each Galzemic XL 8 mg prolonged-release capsule contains 8 mg galantamine (as hydrobromide). Each Galzemic XL 16 mg prolonged-release capsule contains 16 mg galantamine (as hydrobromide). Each Galzemic XL 24 mg prolonged-release capsule contains 24 mg galantamine (as hydrobromide).
- The other ingredients are:
Capsule content: Cellulose microcrystalline, Hypromellose, Ethylcellulose and Magnesium stearate.
Capsule shell:
8mg: Gelatin and Titanium dioxide (E171).
16 mg: Gelatin, Titanium dioxide (E171) and Red iron oxide (E172).
24 mg: Gelatin, Titanium dioxide (E171), Indigo carmine (E132), Erythrosin (E127), Red Iron Oxide (E172) and Yellow iron oxide (E172).

What Galzemic XL looks like and contents of the pack

Galzemic XL 8 mg prolonged-release capsules, hard are opaque white size 2 hard gelatin capsules containing one round biconvex tablet.

Galzemic XL 16 mg prolonged-release capsules, hard are opaque flesh size 2 hard gelatin capsules containing two round biconvex tablets.

Galzemic XL 24 mg prolonged-release capsules, hard are opaque orange size 2 hard gelatin capsules containing three round biconvex tablets.

The capsules are available in the following packs: Transparent PVC/PE/PVDC – Aluminium blisters with 7, 28, 30, 56, 84, 90, 98, 250, 500 prolonged-release capsules

or

White opaque polyethylene high density container with screw cap with 100 prolonged-release capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Zentiva Pharma UK Limited
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Manufacturer(s)

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