

Gatalin XL 8mg prolonged-release capsules, hard Gatalin XL 16mg prolonged-release capsules, hard Gatalin XL 24mg prolonged-release capsules, hard

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

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

Gatalin XL contains the active substance galantamine, an antedementia 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. Gatalin 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 Gatalin XL

Do not take Gatalin XL

- 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 Gatalin 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

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

Before you take Gatalin 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 Gatalin XL is suitable for you, or if the dose needs to be changed.

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

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

Children and adolescents

This medicine is not recommended for children and adolescents.

Other medicines and Gatalin XL

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

Gatalin XL must not be taken 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 Gatalin XL. These include:

- paroxetine or fluoxetine (antidepressants)
- quinidine (for uneven heartbeat)
- 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)
- medicines affecting the QTc interval.

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

This medicine may affect some anaesthetics. If you are going to have an operation under a general anaesthetic, tell the doctor that you are taking Gatalin 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 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.

You should not breast feed while you are taking Gatalin XL.

Driving and using machines

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

3. How to take Gatalin 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 Gatalin 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 Gatalin XL to take

You will start treatment with Gatalin XL at a low dose. The recommended starting dose is 8mg, 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 24mg, 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 that the effect of Gatalin 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 liver or kidney problems, your doctor may give you a reduced dose of Gatalin XL or may decide this medicine is not suitable for you.

Switching from taking galantamine tablets or oral solution to galantamine prolonged release capsules

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

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

How to take Gatalin XL

Gatalin XL is for oral use.

The capsules must be swallowed whole and NOT chewed or crushed. Take your dose of Gatalin XL once a day in the morning, with water or other liquids. Try to take this medicine with food.

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

If you take more Gatalin XL than you should

If you take too much Gatalin 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 Gatalin 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 Gatalin XL

Check with your doctor before you stop taking Gatalin 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 generalised exanthematous pustulosis).
 - Rash that may blister, with spots that look like small targets.

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

- **Heart problems** including changes in heartbeat (such as a slow beat, extra beats) or 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 Gatalin XL (may affect up to 1 in 10 people).
- **Fits (seizures)**. These are uncommon in people taking Gatalin XL (may affect up to 1 in 100 people).

You must stop taking Gatalin 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 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 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 (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 Gatalin 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 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 Gatalin XL contains:

The active substance is galantamine.

- Each Gatalin XL 8mg prolonged-release capsule contains 8mg galantamine (as hydrobromide)
- Each Gatalin XL 16mg prolonged-release capsule contains 16mg galantamine (as hydrobromide)
- Each Gatalin XL 24mg prolonged-release capsule contains 24mg galantamine (as hydrobromide)

The other ingredients are:

Capsule contents:

Cellulose microcrystalline, Hypromellose, Ethylcellulose and Magnesium stearate.

Capsule shell:

8mg: Gelatin and Titanium dioxide (E171).

16mg: Gelatin, Titanium dioxide (E171) and Red iron oxide (E172).

24mg: Gelatin, Titanium dioxide (E171), Indigo carmine (E132), Erythrosin (E127), Red iron oxide (E172) and Yellow iron oxide (E172).

What Gatalin XL looks like and contents of the pack

8mg: opaque, white size 2 hard gelatin capsules containing one round biconvex tablet

16mg: opaque, flesh-coloured size 2 hard gelatin capsules containing two round biconvex tablets

24mg: opaque orange size 2 hard gelatin capsules containing three round biconvex tablets

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

The capsules are available in transparent PVC/PE/PVDC-Aluminum blisters with 1, 7, 14, 28, 30, 56, 60, 84, 90, 300 prolonged release capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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