Package leaflet: Information for the user

Gaalin 8 mg prolonged-release capsules, hard
Gaalin 16 mg prolonged-release capsules, hard
Gaalin 24 mg 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 Gaalin is and what it is used for
2. What you need to know before you take Gaalin
3. How to take Gaalin
4. Possible side effects
5. How to store Gaalin
6. Contents of the pack and other information

1. What Gaalin is and what it is used for

Gaalin 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. Gaalin 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 Gaalin

Do not take Gaalin
- 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

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

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

Before you take Gaalin, 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 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 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 Gaalin 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 Gaalin is not suitable for you.

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

Children and adolescents
Gaalin is not recommended for children and adolescents.

Other medicines and Gaalin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Gaalin 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 Gaalin. 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 heart-beat, your doctor may check your heart using an electrocardiogram (ECG)

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

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

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

Pregnancy, breast-feeding and fertility
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 breastfeed while you are taking Gaalin.

Driving and using machines
Gaalin may make you feel dizzy or sleepy, especially during the first few weeks of treatment. If Gaalin affects you, do not drive or use any tools or machinery.

Gaalin contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'

3. How to take Gaalin

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 Galantamine prolonged-release capsules, carefully read the instructions under 'Switching from taking Galantamine tablets or oral solution to Galantamine capsule in this section.

How much to take

You will start treatment with Gaalin at a low dose. The usual starting dose is 8 mg, 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, 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 Gaalin 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 Gaalin, 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 Galantamine 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 Galantamine prolonged-release capsules.

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

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

P1542642

Black A/s: 190 x 340 mm

AUROBINDO Packaging Development	Product: Gaalin	Component: Leaflet	Item Code: P1542642	Date & Time: 04.06.2026 & 11:30 AM
	Customer / Country: Milpharm_Unit-7	Version No.: 00	Reason Of Issue: Revision	Reviewed / Approved by
Team Leader: Ramesh P	Dimensions: 190 x 340 mm	No. of Colours : 01		
Initiator: Narender				
Artist: Vision Graphic Designers	Pharmacode: 42642			
Additional Information : Supersede Item Code: P1540136				Sign / Date

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

If you take more Gaalin than you should
If you take too much Gaalin, 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 heart beat, fits (seizures) and loss of consciousness.

If you forget to take Gaalin
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 Gaalin

Check with your doctor before you stop taking Gaalin. 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 Gaalin 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 Gaalin (may affect up to 1 in 1,000 people).

Heart problems, including changes in heart beat (such as a slow beat, extra beats) or palpitations (heart beat feels fast or uneven). Heart problems may show as an abnormal tracing on an electrocardiogram (ECG), and can be common in people taking Gaalin (may affect up to1 in 10 people).
Fits (seizures). These are uncommon in people taking Gaalin (may affect up to 1 in 100 people).

You must stop taking Gaalin and get help immediately if you notice any of the side effects 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
- Nightmares

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 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 Gaalin

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 blister or carton 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 Gaalin contains
- The active substance is galantamine.
  Each prolonged-release capsule contains 8 mg galantamine (as hydrobromide).
  Each prolonged-release capsule contains 16 mg galantamine (as hydrobromide).
  Each prolonged-release capsule contains 24 mg galantamine (as hydrobromide).
- The other ingredients are

Capsule Fill: Cellulose, microcrystalline (Grade -102), talc, hydroxy propyl cellulose, silica, colloidal anhydrous, magnesium Stearate
Capsule Shell:
8 mg: Titanium Dioxide (E171), sodium lauryl sulfate, gelatin
16 mg: Titanium Dioxide (E171), iron oxide red (E172), sodium lauryl sulfate, gelatin
24 mg: Titanium Dioxide (E171), iron oxide red (E172), iron oxide yellow (E172) sodium lauryl sulfate, gelatin
Printing ink: Shellac, black iron oxide (E172)

What Gaalin looks like and contents of the pack

Prolonged-release capsule, hard.

Gaalin 8 mg prolonged-release capsules, hard:
White opaque, Size “1” hard gelatin capsules with inscription “A” over the cap & “8” over the body containing one white to off white round, biconvex mini tablet.

Gaalin 16 mg prolonged-release capsules, hard:
Pink opaque, Size “1” hard gelatin capsules with inscription “A” over the cap & “16” over the body containing two white to off white round, biconvex mini tablets.

Gaalin 24 mg prolonged-release capsules, hard:
Caramel opaque, Size “1” hard gelatin capsules filled with inscription “A” over the cap & “24” over the body containing three white to off white round, biconvex mini tablets.

Gaalin prolonged-release capsules, hard are available in blister packs.

Pack sizes:
Blister packs: 28 and 30 prolonged-release capsules, hard

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Milpharm Limited
1 Roundwood Avenue
Stockley Park, Uxbridge
UB11 1AF
United Kingdom

Manufacturer
APL Swift Services (Malta) Ltd,
HF26, Hal Far Industrial EstateHal Far,
Birzebbugia, BBG 3000, Malta.

or

Milpharm Limited
1 Roundwood Avenue
Stockley Park, Uxbridge
UB11 1AF, United Kingdom
or

Generis Farmacêutica, S.A.,
Rua João de Deus, 19, 2700-487 Amadora,
Portugal

This leaflet was last revised in 06/2026.

Ref Ver: 01

P1542642