PACKAGE LEAFLET: INFORMATION FOR THE USER

Galantax XL 8mg Prolonged-release Capsules, hard
Galantax XL 16mg Prolonged-release Capsules, hard
Galantax 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.

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

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

Galantax XL is an antidementia medicine used to treat the symptoms of mild to moderately severe dementia of the Alzheimer type, a disease that alters brain function.

The symptoms of Alzheimer's disease include increasing memory loss, confusion and behavioural changes. As a result, it becomes more and more difficult to carry out normal daily activities.

These symptoms are believed to be due to a lack of acetylcholine, a substance responsible for sending messages between brain cells. Galantax XL increases the amount of acetylcholine in the brain and so could improve the symptoms of the disease.

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

Do not take Galantax XL
- If you are allergic to galantamine or any of the other ingredients of this medicine (listed in section 6).
- If you have severe liver and/or severe kidney disease

Warnings and precautions
Talk to your doctor or pharmacist before taking Galantax XL.

Galantax XL should be used in Alzheimer's disease and not other forms of memory loss or confusion.

Medicines are not always suitable for everyone. Your doctor needs to know before you take Galantax XL if you suffer from or have suffered in the past from any of the following conditions:
- liver or kidney problems
- a heart disorder (e.g. angina, heart attack, heart failure, slow or irregular pulse)
- electrolyte disturbances (e.g. decreased/increased blood potassium levels)
- peptic (stomach) ulcer disease
- acute abdominal pain
- a disorder of the nervous system (like epilepsy or Parkinson's disease)
- a respiratory disease or infection that interferes with breathing (like asthma, obstructive pulmonary disease, or pneumonia)
- if you recently had an operation on the gut or bladder
- if you have difficulties passing urine

If you need an operation which requires a general anaesthetic, you should inform the doctor that you are taking Galantax XL.

Your doctor will then decide whether treatment with Galantax XL is suitable for you or if the dose needs to be changed.

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

Galantax XL 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 muscular weakness)
- pilocarpine (for dry mouth or dry eyes) if taken by mouth.

Some medicines can affect the way Galantax XL works, or Galantax XL itself can reduce the effectiveness of other medicines taken at the same time. These include:
- paroxetine or fluoxetine (antidepressants)
- quinidine (used for heart rhythm problems)
- ketoconazole (antifungal)
- erythromycin (antibiotic)
- ritonavir (antiviral – HIV protease inhibitor).

Your doctor may prescribe a smaller dose of Galantax XL if you are also taking any of the medicines listed above.

Some medicines can increase the number of side effects caused by Galantax XL, these include:
- non-steroidal anti-inflammatory painkillers (e.g. ibuprofen) which can increase the risk of ulcers
- medicines taken for heart disorders or high blood pressure (e.g. digoxin, amiodarone, atropine, beta-blockers, or calcium channel blocking agents). If you take medicines for an irregular heart-beat, your doctor may consider an electrocardiogram (ECG).

If you need an operation which requires a general anaesthetic, you should inform the doctor that you are taking Galantax XL.

Your doctor will also check your weight regularly while you are taking Galantax XL.

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

Galantax XL with food and drink
Galantax XL should be taken with food if possible.

See section 3 of this leaflet for full details about how to take this medicine.

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 breastfeed while you are taking Galantax XL.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Galantax XL may cause dizziness or drowsiness, especially during the first few weeks of treatment. If you experience these symptoms, do not drive or use any tools or machinery.

3. How to take Galantax 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.

Galantax XL is started at a low dose. Your doctor may then tell you to slowly increase the dose of Galantax XL that you take to find the most suitable dose for you.

1. The treatment is started with 8 mg taken once daily. After 4 weeks of treatment, the dose is increased.
2. You would then take 16 mg once daily. After another 4 weeks of treatment at the earliest, your doctor may decide to increase the dose again.
3. You would then take 24 mg once daily.

Your doctor will explain what dose to start with and when the dose should be increased.

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

Liver or kidney disease
- If you have mild liver or kidney disease, treatment is started with 8 mg capsule once daily in the morning.
- If you have moderate liver or kidney disease, treatment is started with 8 mg capsule once every other day in the morning. After one week, begin taking 8 mg capsule once daily in the morning. Do not take more than 16 mg once daily.
- If you have severe liver and/or kidney disease, do not take Galantax XL.

How do I switch from taking Galantamine immediate release tablets or oral solution to Galantamine prolonged release capsules?
If you are currently taking Galantamine immediate release tablets or oral solution, your doctor may decide to switch you to Galantamine prolonged-release capsules.
- Take your last dose of Galantamine immediate release 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 Galantax XL, DO NOT take Galantamine immediate release tablets or oral solution.

Use in children
Galantax XL is not recommended for children.

Method of administration
Galantax XL should be swallowed whole, NOT chewed or crushed. Galantax XL should be taken in the morning, with water or other liquids, and preferably with food. Drink plenty of liquids during your treatment with Galantax XL, to keep yourself hydrated.

If you take more Galantax XL than you should
If you take too much Galantax XL, contact a doctor or hospital straight away. Take along any remaining capsules and the packaging with you. Signs or symptoms of overdose may include, among others: severe nausea, vomiting, muscle weakness, slow heart beat, seizures and loss of consciousness.

If you forget to take Galantax 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, you should contact your doctor.

If you stop taking Galantax XL
You should consult your doctor before you stop taking Galantax 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.

Some of these effects may be due to the disease itself.

Stop taking your medicine and see a doctor immediately if you experience:
- Heart problems including changes in heart beat (slow or irregular)
- Palpitations (pounding heart beat)
- Conditions like blackout
- An allergic reaction. The signs may include a rash, swallowing or breathing problems, or swelling of your lips, face, throat or tongue.

Side effects include:

Very common (may affect more than 1 in 10 people)
- Feeling sick and/or vomiting. If these undesired effects occur, they are mainly experienced early on in the treatment or when the dose is increased. They tend to disappear gradually as the body gets used to the treatment and generally will not last for more than a few days. If you have these effects, your doctor may recommend that you drink more liquids and, if necessary, may prescribe a medicine to stop you being sick.

Common (may affect up to 1 in 10 people)
- Weight loss
- Loss of appetite
- Decreased appetite
- Slow heart beat
- Feeling faint
- Dizziness
- Trembling
- Headache
- Drowsiness
- Abnormally tired
- Stomach pain or discomfort
- Diarrhoea
- Indigestion
- Increased sweating
- Muscle spasms
- Falling
- High blood pressure
- Feeling weak
- General feeling of discomfort
- Seeing, feeling, or hearing things that are not real (hallucinations)
- Feeling sad (depression).

Uncommon (may affect up to 1 in 100 people)
- Increased liver enzymes in the blood (laboratory test result that tells how well your liver is working)
- Possible skipped heart beat
- Disturbance in the mechanism of conducting impulses in the heart
- Sensation of abnormal heart beats (palpitations)
- Tingling, pricking, or numbness of the skin
- Change in the sense of taste
- Excessive sleepiness
- Blurred vision
- Ringing or buzzing in the ears (tinnitus)
- Feeling the need to vomit
- Muscle weakness
- Excessive water loss in the body
- Low blood pressure
- Reddening of the face
- Allergic reaction

Rare (may affect up to 1 in 1,000 people)
- Inflammation of the liver (hepatitis)

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Galantax 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 foil after the letters EXP. The expiry date refers to the last day of that month.

This medicinal product 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 Galantax XL contains:
The active substance is galantamine.
- Each Galantamine 8 mg prolonged-release capsule, hard contains 8 mg galantamine (as hydrobromide)
- Each Galantamine 16 mg prolonged-release capsule, hard contains 16 mg galantamine (as hydrobromide)
- Each Galantamine 24 mg prolonged-release capsule, hard contains 24 mg galantamine (as hydrobromide)

The other ingredients are:

Capsule content
Cellulose microcrystalline, hypromellose, ethylcellulose, magnesium stearate.

Capsule shell
8 mg: Gelatin, titanium dioxide (E171).
16 mg: Gelatin, titanium dioxide (E171), red iron oxide (E172).
24 mg: Gelatin, titanium dioxide (E171), indigo carmine (E132), erythrosine (E127), red iron oxide (E172), yellow iron oxide (E172).

What Galantax XL looks like and contents of the pack
Galantamine prolonged-release capsules, hard are available in three strengths, each of which can be recognised by its colour:
8 mg: White capsules containing one round biconvex prolonged-release tablet
16 mg: Pale pink capsules containing two round biconvex prolonged-release tablets
24 mg: Orange capsules containing three round biconvex prolonged-release tablets

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

The capsules are available in the following blister packs:
8 mg: 10, 28, 30, 56, 90, 100, 300 prolonged release capsules
16 mg: 10, 28, 30, 84, 90, 100, 300 prolonged release capsules
24 mg: 10, 28, 30, 84, 90, 100, 300 prolonged release capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer
Pharmathen S.A., 6 Dervenakion str., 15351 Pallini, Athens, Greece

Pharmathen International S.A., Industrial Park Sapes, Rodopi Prefecture, Block No. 5, Rodopi 69300, Greece

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

STADA Arzneimittel AG, Stadastrasse 2–18, 61118 Bad Vilbel, Germany

PharmaCoDane ApS, Marielundvej 46A, 2730 Herlev, Denmark

This medicinal product is authorised in the Member States of the EEA under the following names:

Germany	Galantamin STADA 8mg, 16mg, 24mg Hartkapseln, retardiert
Austria	Galantamin STADA 8mg, 16mg, 24mg Retardkapseln
Denmark	Galantamin STADA 8mg, 16mg, 24mg depotkapslar, hårde
Spain	Galantamina STADA 8mg, 16mg, 24mg cápsulas de liberación prolongada EFG
Finland	Galantamin STADA 8mg, 16mg, 24mg depotkapseli, kova
France	Galantamine EG 8mg, 16mg, 24mg gélule à liberation prolongée
Ireland	Galantax XL 8mg, 16mg, 24mg prolonged-release capsules
Netherlands	Galantamine retard CF 8mg, 16mg, 24mg harde capsules met verlengde afgigte
Sweden	Galantamin STADA 8mg, 16mg, 24mg depotkapslar, harda

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