

**Package leaflet: Information for the user**

<b>Galantamine 8 mg prolonged-release capsules, hard</b>
<b>Galantamine 16 mg prolonged-release capsules, hard</b>
<b>Galantamine 24 mg prolonged-release capsules, hard</b>

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

**1. What <Invented name> is and what it is used for**

<Invented name> 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. <Invented name> 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 <Invented name>****DO NOT take <Invented name>**

- If you are allergic to galantamine or 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 <Invented name>. This medicine is only used in Alzheimer's disease, and is not recommended for other types of memory loss or confusion.

**Serious side effects**

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

**Before you take <Invented name>**, 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)
- 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 <Invented name> 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 <Invented name> is not suitable for you.

**<Invented name> can cause weight loss.** Your doctor will check your weight regularly while you are taking <Invented name>.

### **Children and adolescents**

<Invented name> is not recommended for children and adolescents.

### **Other medicines and <Invented name>**

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

<Invented name> 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 <Invented name>. 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).

Your doctor may give you a lower dose of <Invented name> if you are also taking some of these medicines.

<Invented name> may affect some anaesthetics. If you are going to have an operation under a general anaesthetic, tell the doctor that you are taking <Invented name>, 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 breastfeed while you are taking <Invented name>.**

**Driving and using machines**

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

**3. How to take <Invented name>**

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 <Invented name> prolonged-release capsules, carefully read the instructions under 'Switching from taking galantamine tablets or oral solution to <Invented name> capsules' in this section.

**How much to take**

You will start treatment with <Invented name> 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 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 <Invented name> 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 <Invented name>, or may decide this medicine is not suitable for you.

**Switching from taking galantamine tablets or oral solution to <Invented name> capsules**

If you are currently taking galantamine tablets or oral solution, your doctor may decide to switch you to <Invented name> 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 <Invented name> prolonged-release capsules.

**DO NOT take more than one capsule in a day. While you are taking once-daily <Invented name>, DO NOT take galantamine tablets or oral solution.**

**How to take**

<Invented name> must be swallowed whole and NOT chewed or crushed. Take your dose of <Invented name> once a day in the morning, with water or other liquids. Try to take <Invented name> with food. Drink plenty of liquids during your treatment with <Invented name>, to keep yourself hydrated.

**If you take more <Invented name> than you should**

If you take too much <Invented name>, contact a doctor or hospital straight away. Take along any remaining capsules and the packaging with you. The signs of overdose may include

- severe nausea and vomiting.

- weak muscle, slow heart beat, fits (seizures) and loss of consciousness.

**If you forget to take <Invented name>**

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 <Invented name>**

Check with your doctor before you stop taking <Invented name>. 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 <Invented name> 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 <Invented name> (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 <Invented name> (may affect up to 1 in 10 people).

**Fits (seizures)**. These are uncommon in people taking <Invented name> (may affect up to 1 in 100 people).

**You must stop taking <Invented name> 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 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 real (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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system](#) listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store <Invented name>

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 <Invented name> 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 (E 132), Erythrosin(E 127), Red Iron Oxide (E 172), Yellow iron oxide (E 172).

#### **What <Invented name> 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 tablet

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**

<To be completed nationally>

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

Germany	Galantamin STADA 8 mg, 16 mg, 24 mg Hartkapseln, retardiert
Denmark	Galantamin STADA 8 mg, 16 mg, 24 mg depotkapslar, hårde
Spain	Galantamina STADA 8 mg, 16 mg, 24 mg cápsulas de liberación prolongada EFG
Finland	Galantamin STADA 8 mg, 16 mg, 24 mg depotkapseli, kova
France	Galantamine EG 8 mg, 16 mg, 24 mg gélule à libération prolongée
Netherlands	Galantamine retard CF 8 mg, 16 mg, 24 mg harde capsules met verlengde afgifte
Sweden	Galantamin STADA 8 mg, 16 mg, 24 mg depotkapslar, harda

**This leaflet was last revised in February 2016.**