Package leaflet: Information for the patient

Galantamine Krka 8 mg
prolonged-release capsules, hard
Galantamine Krka 16 mg
prolonged-release capsules, hard
Galantamine Krka 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 Galantamine Krka is and what it is used for

Galantamine Krka contains the active substance 'galantamine' that is 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. Galantamine Krka 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 Galantamine Krka

Do not take Galantamine Krka
- 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 Galantamine Krka.
This medicine is only used in Alzheimer's disease and is not recommended for other types of memory loss or confusion.

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

Before you take Galantamine Krka, 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, 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)
- 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 Galantamine Krka 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 Galantamine Krka is not suitable for you.

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

Children and adolescents
Galantamine Krka is not recommended for children and adolescents.

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

Galantamine Krka 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 Galantamine Krka. 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),
- medicines affecting the QTc interval.

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

Galantamine Krka may affect some anaesthetics. If you are going to have an operation under a general anaesthetic, tell the doctor that you are taking Galantamine Krka, 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 for advice before taking this medicine.

You should not breastfeed while you are taking Galantamine Krka.

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

Galantamine Krka contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per prolonged-release capsule, that is to say essentially "sodium-free".

3. How to take Galantamine Krka

Always take this medicine exactly as your doctor 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 Krka capsules' in this section.

How much to take
You will start treatment with Galantamine Krka 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 Galantamine Krka 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 Galantamine Krka, or may decide this medicine is not suitable for you.

Switching from taking galantamine tablets or oral solution to Galantamine Krka capsules
If you are currently taking galantamine tablets or oral solution, your doctor may decide you should switch to Galantamine Krka 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 Krka prolonged-release capsule.

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

How to take Galantamine Krka
Galantamine Krka capsules must be swallowed whole, NOT chewed or crushed.
If you find the capsules difficult to swallow, you may empty the capsule and swallow the content whole - DO NOT chew or crush the contents.
Take your dose of Galantamine Krka once a day in the morning, with water or other liquids. Try to take Galantamine Krka with food. Drink plenty of liquids while you are taking Galantamine Krka, to keep yourself hydrated.

If you take more Galantamine Krka than you should
If you take too much Galantamine Krka, contact a doctor or hospital straight away. Take any remaining capsules and the packaging with you. Signs of overdose may include:
- severe nausea and vomiting,
- muscle weakness, slow heartbeat, fits (seizures) and loss of consciousness.

If you forget to take Galantamine Krka
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 Galantamine Krka
You should consult your doctor before you stop taking Galantamine Krka. 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 your 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 of the 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 galantamine (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 Galantamine Krka (may affect up to1 in 10 people).

Fits (seizures). These are uncommon in people taking Galantamine Krka (may affect up to 1 in 100 people).

You must stop taking Galantamine Krka 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 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, may prescribe a medicine to stop you being sick.

Common side effects (may affect up to 1 in 10 people):
- Weight loss, decreased appetite
- Seeing, feeling, or hearing things that are not there (hallucinations)
- Depression
- Feeling dizzy or fainting
- Muscle tremor 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 the 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):
- Inflammation of the 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 Yellow Card Scheme, Website: 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 Galantamine Krka

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 and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original package in order to protect from moisture.

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 Galantamine Krka contains
- The active substance is galantamine.
  8 mg: Each prolonged-release capsule, hard contains 8 mg galantamine (as hydrobromide).
  16 mg: Each prolonged-release capsule, hard contains 16 mg galantamine (as hydrobromide).
  24 mg: Each prolonged-release capsule, hard contains 24 mg galantamine (as hydrobromide).
- The other ingredients in the prolonged-release tablet core are sodium laurilsulfate, ammonio methacrylate copolymer (type B), hypromellose, carbomers, hydroxypropylcellulose, magnesium stearate and talc. See section 2 "Galantamine Krka contains sodium".
- The other ingredients in the 8 mg capsule shell are gelatin, titanium dioxide (E171) and black ink (shellac, propylene glycol, concentrated ammonia solution, black iron oxide (E172), potassium hydroxide).
- The other ingredients in the 16 mg and 24 mg capsule shell are gelatin, titanium dioxide (E171), red iron oxide (E172), yellow iron oxide (E172) and black ink (shellac, propylene glycol, concentrated ammonia solution, black iron oxide (E172), potassium hydroxide).

What Galantamine Krka looks like and contents of the pack
8 mg: White capsules size 2 (capsule length: 17.6 - 18.4 mm) with G8 imprinted on the capsule's cap. Content of capsule is one white oval, prolonged-release tablet core.
16 mg: Pink capsules size 1 (capsule length: 19.0 - 19.8 mm) with G16 imprinted on the capsule's cap. Content of capsule are two white, oval, prolonged-release tablet cores.
24 mg: Orange pink capsules size 0 el (capsule length: 23.8 - 24.6 mm) with G24 imprinted on the capsule's cap. Content of capsule are three white, oval, prolonged-release tablet cores.

Capsules are available in cartons of 10, 14, 28, 30, 56, 60, 84, 90 and 100 prolonged-release capsules, hard in blisters.
Not all pack sizes may be marketed.

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