

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr MYLAN-GALANTAMINE ER

Galantamine Extended-Release Capsules, USP

Read this carefully before you start taking **MYLAN-GALANTAMINE ER** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **MYLAN-GALANTAMINE ER**.

What is MYLAN-GALANTAMINE ER used for?

MYLAN-GALANTAMINE ER is used to treat the symptoms of mild to moderate Alzheimer's disease (a type of dementia).

How does MYLAN-GALANTAMINE ER work?

MYLAN-GALANTAMINE ER is a type of drug called a "cholinesterase inhibitor." Low amounts of acetylcholine in the brain might be the cause of Alzheimer's disease. MYLAN-GALANTAMINE ER helps increase the amount of acetylcholine in the brain which improves memory.

What are the ingredients in MYLAN-GALANTAMINE ER?

Medicinal ingredients: galantamine hydrobromide

Non-medicinal ingredients:

colloidal silicon dioxide, gelatin, hydrogenated vegetable oil, magnesium stearate, polyvinyl acetate, povidone, sodium lauryl sulphate and titanium dioxide. The 16 mg capsule also contains FD&C Red 40. The 24 mg capsule also contains FD&C Blue 1, FD&C Yellow 6 and red iron oxide.

Printing Ink: Ink: Black Iron Oxide, Butyl Alcohol, Dehydrated Alcohol, Isopropyl Alcohol, Potassium Hydroxide, Propylene Glycol and Shellac.

MYLAN-GALANTAMINE ER comes in the following dosage forms:

Extended release capsules: 8 mg, 16 mg, 24 mg

Do not use MYLAN-GALANTAMINE ER if:

you or the person you are caring for:

- is allergic to:
 - galantamine hydrobromide
 - any of the other ingredients in MYLAN-GALANTAMINE ER
 - a similar type of medicine to galantamine hydrobromide
- is under 18 years of age

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MYLAN-GALANTAMINE ER. Talk about any health conditions or problems you may have, including if you:

- have a heart condition
- have an ulcer or history of ulcers in the stomach or gut
- have a blockage of the stomach or in the gut
- have seizures [or fits] (such as epilepsy)
- have problems controlling movements of the body or limbs (extrapyramidal disorder)
- have a respiratory disease that affects breathing (such as asthma or obstructive pulmonary disease)
- have problems passing urine
- have an increased risk of developing ulcers (for example, you are taking non-steroidal anti-inflammatory drugs (NSAIDs) or high doses of acetylsalicylic acid [ASA (ASPIRIN)])
- have liver or kidney problems
- are pregnant or planning to become pregnant
- are breast-feeding or planning to breast-feed
- are planning to have or have had an operation with general anesthesia (medication that puts you to sleep)

Other warnings you should know about:

Talk to your doctor right away if you

- have any skin rashes or inflammation,
- blisters or
- swelling of the skin.

Also tell your doctor if you recently had an operation on the stomach, gut or bladder.

MYLAN-GALANTAMINE ER can cause weight loss. Your doctor will check your weight regularly while you are taking MYLAN-GALANTAMINE ER.

Driving and using machines: Your doctor will tell you whether your illness allows you to drive vehicles and use machines safely. MYLAN-GALANTAMINE ER may make you feel dizzy or sleepy, especially during the first few weeks of treatment. If MYLAN-GALANTAMINE ER affects you, do not drive or use any tools or machinery.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

MYLAN-GALANTAMINE ER should not be used with medicines that work in a similar way.

The following may interact with MYLAN-GALANTAMINE ER:

- anticholinergics (such as drugs for diarrhea, Parkinson's disease, or airway spasms)
- medicines taken for heart conditions or high blood pressure (such as digoxin or beta-blockers)
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) or high doses of acetylsalicylic acid [ASA (ASPIRIN)], which can increase the risk of ulcers
- antidepressants (such as amitriptyline, fluoxetine, fluvoxamine, or paroxetine)
- ketoconazole (an antifungal)
- erythromycin (an antibiotic)
- quinidine (for irregular heartbeat)

MYLAN-GALANTAMINE ER may affect some anesthetics. If you are going to have an operation under a general anesthetic, tell the doctor that you are taking MYLAN-GALANTAMINE ER, well in advance.

How to take MYLAN-GALANTAMINE ER:

- Take exactly as your healthcare professional has told you.
- Check with your healthcare professional if you are not sure.
- Swallow capsules whole with fluids.
- Take MYLAN-GALANTAMINE ER for as long as your healthcare professional prescribes it. Do not stop taking this medicine unless your healthcare professional tells you to.

Usual dose:

Take your dose of MYLAN-GALANTAMINE ER once a day in the morning, with water or other liquids. Try to take MYLAN-GALANTAMINE ER with food.

- 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 good for you.
- The maximum dose is 24 mg, taken once a day.

DO NOT take more than one capsule in a day unless instructed to by your doctor.

If you have liver or kidney problems, your doctor may give you a lower dose of MYLAN-GALANTAMINE ER, or may decide this medicine is not good for you.

While you are taking MYLAN-GALANTAMINE ER

Drink plenty of liquids, to keep yourself hydrated.

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

REMEMBER: This medicine is for you. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms appear to be similar to yours.

Overdose:

The signs of overdose may include:

- severe nausea and vomiting, abdominal cramps, sweating
- weak muscles, difficulty breathing
- seizures (fits)
- low blood pressure, abnormal heart rhythm that may cause loss of consciousness

If you think you, or a person you are caring for, have taken too much MYLAN-GALANTAMINE ER, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take a dose, do not worry, wait and take the next dose at the usual time. Do NOT take two doses at once.

If you miss your dose for a few days or longer, do NOT restart without contacting your doctor.

What are possible side effects from using MYLAN-GALANTAMINE ER?

These are not all the possible side effects you may have when taking MYLAN-GALANTAMINE ER. If you experience any side effects not listed here, tell your healthcare professional.

- abdominal pain, diarrhea, indigestion, decreased appetite
- difficulty swallowing
- weight loss
- flushing
- dehydration (sometimes severe)
- weakness
- fever
- malaise
- leg cramps
- muscle spasms
- tingling in the hands or feet
- ringing in the ears
- headache
- dizziness
- blurred vision
- tiredness, sleepiness or sleeplessness
- depression

- runny nose
- sweating
- urinary tract infection, incontinence
- falling, sometimes resulting in injury
- trembling

If side effects occur, they are mainly experienced early in the treatment or when the dose is increased. Most tend to disappear gradually as the body adapts to the treatment; for example, nausea (feeling sick) and vomiting (being sick) generally pass after a few days. However, you should tell your doctor about any side effects, especially if they persist.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Behavioural Changes: agitation and aggression		✓	
Fainting		✓	
High Blood Pressure: headache, dizziness, vision problems, shortness of breath	✓		
UNCOMMON			
Problems with Heart Rhythm: irregular beating of the heart			✓
Heart Attack: pain or tightness in the chest			✓
Seizures: fits or convulsions			✓
Stroke: sudden weakness or numbness of the face, arms or legs, especially on one side, slurred speech or vision problems			✓
Low Blood Pressure: dizziness, fainting, lightheadedness may occur when you go from lying or sitting to standing up	✓		
Severe confusion			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
Thoughts of suicide or self-harm			✓
VERY RARE			
Stomach Ulcer and Gastrointestinal Hemorrhage: blood in the stools, black, tarry stools, or vomiting blood			✓
Extrapyramidal Disorder: problems controlling movements of the body or limbs, including, but not limited to, stiff limbs, trembling hands, body spasms, upward eye rolling, exaggeration of reflexes, drooling, difficulty moving how and when you want			✓
UNKNOWN			
Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
Decreased Levels of Potassium in the Blood: irregular heartbeats, muscle weakness and generally feeling unwell		✓	
Hallucinations: seeing, feeling or hearing things that are not there			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Stevens-Johnson Syndrome: Severe rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals			✓
Acute Generalized Exanthematous Pustulosis: Red rash covered with small pus-filled bumps that can spread over the body, sometimes with a fever			✓
Erythema Multiforme: Rash that may blister, with spots that look like small targets			✓

If you are caring for a patient with Alzheimer's disease who has new symptoms you should discuss them with his or her doctor.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional. If you experience side effects that are severe, stop taking the drug and contact your doctor immediately.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store MYLAN-GALANTAMINE ER in a cool dry place between 15 to 30°C.

Keep out of reach and sight of children.

Medicines can be kept for a limited period only. Therefore, do not use MYLAN-GALANTAMINE ER after the date (month and year) printed after “EXP”, even if it has been stored properly. Always return old medicines to your pharmacist.

If you want more information about MYLAN-GALANTAMINE ER:

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer’s website www.mylan.ca, or by calling 1-844-596-9526.

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