

PART III: CONSUMER INFORMATION**WARNINGS AND PRECAUTIONS**

**PrPAT-galantamine ER
galantamine hydrobromide
extended release capsules, House Std.**

This leaflet is Part III of a three-part “Product Monograph” published when PAT-galantamine ER (galantamine hydrobromide) was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PAT-galantamine ER. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

PAT-galantamine ER is used to treat the symptoms of mild to moderate Alzheimer’s disease (a type of dementia), a disease 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.

This medication should only be taken after proper diagnosis of your condition has been made by your doctor.

What it does:

This medication is one of a group of drugs called “cholinesterase inhibitors” which are used to treat the symptoms of mild to moderate Alzheimer’s disease. Dementia due to Alzheimer’s disease is believed to be related to lack of a substance in the brain called acetylcholine, a substance which is thought to be necessary for good brain function. PAT-galantamine ER increases the amount of this substance in the brain, improving memory.

When it should not be used:

Do not use PAT-galantamine ER if you/the person you are caring for:

- are/is allergic to galantamine hydrobromide or to any non-medicinal ingredient in the formulation
- have/has ever had an allergic reaction to a similar type of medicine
- are/is a child under 18 years of age

What the medicinal ingredient is:

galantamine hydrobromide

What the nonmedicinal ingredients are:

Diethyl phthalate, ethylcellulose, gelatin, hypromellose, polyethylene glycol, sugar spheres (sucrose and starch) and titanium dioxide. The 16 mg capsule also contains red ferric oxide. The 24 mg capsule also contains red ferric oxide and yellow ferric oxide.

What dosage forms it comes in:

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

BEFORE you use PAT-galantamine ER, talk to your doctor or pharmacist if you/the person you are caring for have, or had, any of the following:

- heart condition
- an ulcer or history of ulcers in the stomach or gut
- a blockage of the stomach or in the gut
- seizures [or fits] (such as epilepsy)
- a respiratory disease that affects breathing (such as asthma or obstructive pulmonary disease)
- problems passing urine
- 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)])
- liver or kidney problems
- pregnant or planning to become pregnant
- breast-feeding or planning to breast-feed
- having an operation with general anesthesia (medication that puts you to sleep)
- taking any other medications, including prescription, over-the-counter, herbal medicines or natural health products

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.

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

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

INTERACTIONS WITH THIS MEDICATION

Always tell your doctor, nurse or pharmacist if you are taking any other medicines, either prescription, over-the-counter, herbal medicines, or natural health products, because taking some medicines together can be harmful.

PAT-galantamine ER should not be used with medicines that work in a similar way.

The following may interact with PAT-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 heart beat).

PAT-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 PAT-galantamine ER, well in advance.

PROPER USE OF THIS MEDICATION

You will start treatment with PAT-galantamine ER at a low dose, and then slowly increase this to find the most suitable dose for you. 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 PAT-galantamine ER is too strong or too weak, talk to your doctor or pharmacist.

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

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 reduced dose of PAT-galantamine ER, or may decide this medicine is not suitable for you.

While you are taking PAT-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 discuss 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:

If you think you/the person you are caring for have/has taken too much PAT-galantamine ER, contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

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.

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 your treatment is interrupted for several days or longer, do NOT re-initiate treatment without contacting your doctor.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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.

Other possible side effects include:

- 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

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Common	Behavioral 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			✓
	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			✓
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			✓
	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 feel unwell in the ways described in this section or any other way, or have any symptoms that you do not understand or find distressing, you should contact your doctor immediately. If you experience side effects that are severe, stop taking the drug and contact your doctor immediately.

This is not a complete list of side effects. For any unexpected effects while taking PAT-galantamine ER, contact your doctor or pharmacist.

HOW TO STORE IT

Store PAT-galantamine ER in a cool dry place between 15 to 30°C.

Keep out of the sight and reach of children.

Medicines can be kept for a limited period only. Therefore, do not use PAT-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.

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.

MORE INFORMATION

For questions, concerns, or the full Product Monograph go to: www.janssen.com/canada
or contact the manufacturer, Patriot, a Division of Janssen Inc., at: 1-800-567-3331 or 1-800-387-8781.

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