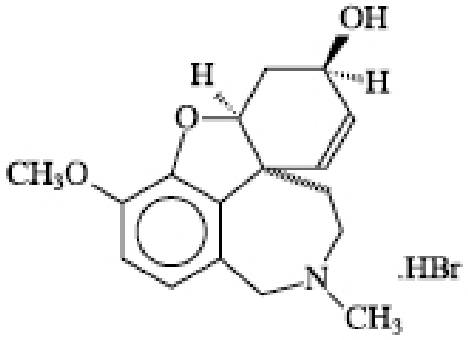
Taj Pharmaceuticals Ltd.

Galantamine Hbr

CAS No. : 1953-04-4

Synonyms:

Reminyl
Reminyl (TN)
6H-Benzofuro[3a,3,2-ef][2]benzazepin-6-ol,4a,- 5,9,10,11,
12-hexahydro-3-methoxy-11- methyl-,hydrobromide,
(4aS,6R,8aS)-Prestwick_236



CAS Number:1953-04-4
Molecular Formula:C17H21NO3.HBr;C17H22BrNO3
Molecular Weight:368.27
EINECS:217-780-5

Galantamine Hydrobromideis galantamine hydrobromide, a reversible, competitive acetylcholinesterase inhibitor.

Galantamine hydrobromide is known chemically as (4aS,6R,8aS)-4a,5,9,10,11,12-hexahydro-3-methoxy-11-methyl-6H-benzofuro[3a,3,2-ef] [2]benzazepin-6-ol hydrobromide.

It has an empirical formula of C17H21NO3 •HBr and a molecular weight of 368.27. Galantamine hydrobromide is a white to almost white powder and is sparingly soluble in water.

USES

Galantamine is used to treat mild to moderate confusion (dementia) related to Alzheimer's disease. It does not cure Alzheimer's disease, but it may improve memory, awareness, and the ability to perform daily functions. This medication works by restoring the balance of certain natural substances (neurotransmitters) in the brain.

HOW TO USE

Take this medication by mouth with food, usually once daily in the morning with breakfast or as directed by your doctor. This medication may be taken on an empty stomach if necessary. Drink plenty of fluids with this medication unless instructed otherwise. To lower your risk of side effects, your dosage will be gradually increased to your target dose. Your dosage is based on your medical condition and response to therapy. Do not take more than the maximum recommended dose of 24 milligrams per day.

Swallow the capsules whole. Do not crush or chew the capsules. Doing so can destroy the long action of the drug and may increase side effects.

If you stop taking galantamine for several days, consult your doctor or pharmacist before restarting it. Your dosage should be reduced to lower the risk of side effects. Your dosage should then be increased gradually. Follow all your doctor's dosing instructions exactly.

Taj Pharmaceuticals Ltd.
Galantamine Hbr
CAS No 1953-04-4

SIDE EFFECTS

Nausea, vomiting, diarrhea, dizziness, loss of appetite, and weight loss may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Tell your doctor immediately if any of these unlikely but serious side effects occur: fainting, unusually slow heartbeat, difficult urination. A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching, swelling, severe dizziness, trouble breathing.

PRECAUTIONS

Before taking galantamine, tell your doctor or pharmacist if you are allergic to it; or to daffodil plants; or if you have any other allergies.

This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: severe liver disease, severe kidney disease.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver problems, kidney problems, stomach/intestinal problems (e.g., ulcers, bleeding), heart problems (e.g., sick sinus syndrome, bradycardia, AV block, arrhythmias), breathing/lung problems (e.g., severe asthma, COPD-chronic obstructive pulmonary disease), seizures, problems urinating (e.g., due to enlarged prostate).
Before having surgery, tell your doctor or dentist that you are taking this medication.

MISSED DOSE

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom. Keep all medicines away from children and pets.

DOSAGE

In patients with moderately impaired hepatic function (Child-Pugh score 7 to 9) and those with moderate renal function impairment, the dose should not exceed 16 mg/day. Not recommended for patients with severe renal (CrCl less than 9 ml/min) or severe hepatic function impairment (Child 10 to 15).

Immediate-Release Tablets and Oral Solution
Adults

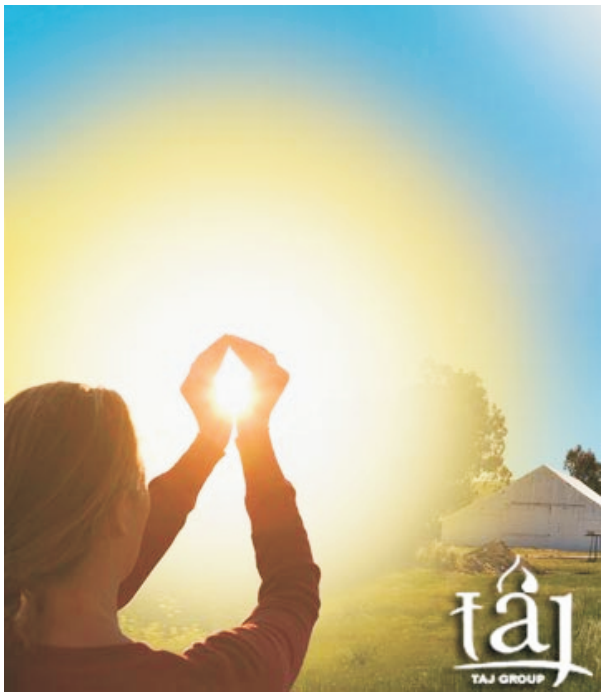
4 mg twice daily. May increase to 8 mg twice daily after 4 wk. A further increase to 12 mg twice daily may be attempted after min 4 wk at previous dose.

Extended-Release Tablets
Adults

8 mg/day. Increase to 16 mg/day after min 4 wk. A further increase to 24 mg/day may be attempted after min 4 wk at previous dose.

General Advice

Administer immediate-release tablets and oral solution twice daily, preferably with morning and evening meal.
Administer extended-release tablets once daily in the morning, preferably with food.



DRUG DESCRIPTION

Galantamine is used to treat mild to moderate confusion (dementia) related to Alzheimer's disease. It does not cure Alzheimer's disease, but it may improve memory, awareness, and the ability to perform daily functions.

This medication works by restoring the balance of certain natural substances (neurotransmitters) in the brain.

Galantamine Hydrobromideis galantamine hydrobromide, a reversible, competitive acetylcholinesterase inhibitor.

Galantamine hydrobromide is a white to almost white powder and is sparingly soluble in water.

Galantamine Hydrobromide, also known as galanthamine, is a cholinesterase (ChE) inhibitor. Compared to donepezil and similar to rivastigmine, Galantamine Hydrobromide requires multiple daily dosages and a slow dosage titration to limit GI side effects.

Hepatotoxicity has not been noted with Galantamine Hydrobromide as it has for tacrine. Overall, Galantamine Hydrobromide appears to be a viable first-line treatment option for Alzheimer's disease; the drug improves cognitive functioning as assessed by the ADAS-cog/11 and the CIBIC-plus scales. Similar to other ChE-inhibitors, the drug does not

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:
http://www.tajapi.com
or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
91 022 30601000.
This leaflet was prepared by
Taj Pharmaceuticals Limited,
Mumbai (India).
MPSTJ278
Last revised: 29 August 2009