

APO-Galantamine MR capsules

Contains the active ingredient galantamine (as galantamine hydrobromide)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about this medicine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine is used for

The name of your medicine is APO-Galantamine MR. It contains the active ingredient galantamine (as hydrobromide).

It is used to treat mild to moderately severe dementia of the Alzheimer's type.

The symptoms of Alzheimer's disease include confusion, memory loss or other changes in behaviour. As the disease progresses, patients find it more and more difficult to carry out their normal daily activities.

The symptoms of Alzheimer's disease are thought to be due to a lack of acetylcholine, a substance which transmits messages between brain cells. Galantamine increases the amount of this substance, to help improve or stabilise the symptoms and therefore slow the progress of Alzheimer's disease.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

There is no evidence that this medicine is addictive.

This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- any medicine containing galantamine
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you have or have had any of the following medical conditions:

- severe liver disease
- severe kidney disease.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- liver and/or kidney disease
- heart problems
- stomach ulcers
- brain disorders, such as Parkinson's disease or fits (seizures)
- problems controlling movements of the body or limbs (extrapyramidal disorders)
- breathing disorders, such as asthma or pneumonia
- recent gut or bladder surgery
- difficulties in passing urine
- attacks of sudden abdominal pain
- low potassium levels in the blood – weakness, muscle cramps, numbness and tingling that begins in the lower extremities.

Tell your doctor if you have mild cognitive impairment, and you have not been diagnosed with Alzheimer's disease.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Do not take this medicine whilst pregnant or breastfeeding until you and your doctor have discussed the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interact with galantamine. These include:

- anticholinergic medicines, used to prevent travel sickness, relieve stomach cramps, spasms or diarrhoea
- cholinergic medicines (e.g. bethanechol and certain medicines used during surgery)
- medicines used to treat Parkinson's disease
- medicines for certain heart problems (e.g. digoxin or quinidine) or to help lower blood pressure (e.g. beta-blockers)
- medicines used for breathing problems
- certain medicines used to treat fungal infections (e.g. ketoconazole) or bacterial infections (e.g. erythromycin)
- certain medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- certain medicines used to treat depression, obsessive compulsive disorder (OCD), panic disorder or anxiety (e.g. paroxetine, fluoxetine or fluvoxamine).

These medicines may be affected by galantamine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Other medicines not listed above may also interact with galantamine.

How to take this medicine

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the directions, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

The dose of galantamine is gradually increased to the most suitable dose. The necessary dosage steps should be determined by your doctor to suit your needs.

The following scheme is an example of how your doctor may increase the dose:

- Start with 8 mg a day.
- After four weeks of treatment, raise the dose to 16 mg a day.
- After at least another four weeks of treatment, raise the dose to 24 mg a day.

For long-term treatment, up to 24 mg a day is usually suitable, but your doctor will determine the dose that is best for you.

How to take it

APO-Galantamine MR capsules should be taken once a day, preferably with food.

Swallow the capsules whole – the contents should not be crushed and sprinkled on food.

Be sure to drink plenty of liquids during your treatment with galantamine to keep yourself hydrated.

When to take it

Take this medicine in the morning.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

If treatment is discontinued for more than several days, tell your doctor. Your doctor will need to restart your treatment at the lowest dose. This will minimise the chance of experiencing side effects.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose when you are meant to.

Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think

that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of overdose can include:

- muscle weakness or twitches
- severe nausea, vomiting, gastrointestinal cramping, salivation, teary eyes, urination, defecation, sweating, slow heart rate, low blood pressure, collapse and convulsions
- difficulty breathing.

While you are taking this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Galantamine may cause dizziness or drowsiness in some people, especially during initial treatment.

Alzheimer's disease may reduce your ability to drive or operate machinery.

You and your doctor should monitor your weight while taking this medication.

Weight loss is associated with this medicine and is common for people with Alzheimer's.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.

All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following:

- nausea, vomiting or diarrhoea
- stomach pain, discomfort, indigestion or difficulty swallowing

- tiredness or weakness
- muscle cramps, spasms or trembling
- numbness and tingling or burning sensations
- headache
- ringing in the ears
- blurred vision
- dehydration (sometimes severe); thirst or lack of fluids
- hallucinations (seeing, feeling or hearing things that are not there)
- feeling depressed or having thoughts of harming yourself
- low blood pressure – dizziness or light-headedness
- high blood pressure
- slow, fast or irregular heart beat
- increased sweating
- changes in taste
- loss of appetite or weight loss
- fainting or falling (sometimes resulting in injury)
- problems controlling movements of the body or limbs (extrapyramidal disorder)
- abnormal liver test results.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- yellowing of the skin and eyes, light coloured bowel motions, or dark coloured urine
- vomiting blood or material that looks like coffee grounds
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- fainting, especially if you have a slow or irregular heart beat
- fits (seizures)
- pain or tightness in the chest
- flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters
- widespread severe rash with peeling skin or white pus-filled spots which may be accompanied by fever, flu-like symptoms, blisters in the mouth, eyes, and/or genitals (Stevens-Johnson syndrome or Acute generalized exanthematous pustulosis)
- symptoms of stroke which can include collapsing, numbness or weakness of arms or legs, headache, dizziness and confusion, visual disturbance, difficulty swallowing, slurred speech and loss of speech
- symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some patients.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What APO-Galantamine looks like

APO-Galantamine MR modified release capsules are available in blister packs of 28 capsules.

8 mg modified release capsules

White opaque capsules containing one round biconvex tablet. AUST R 182030.

16 mg modified release capsules

Flesh opaque capsules containing two round biconvex tablets. AUST R 182041.

24 mg modified release capsules

Orange opaque capsules containing three round biconvex tablets. AUST R 182034.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each capsule contains 8, 16 or 24 mg of galantamine (as hydrobromide) as the active ingredient.

It also contains the following inactive ingredients, that are common to all three strengths:

- microcrystalline cellulose
- hypromellose
- ethylcellulose
- magnesium stearate
- titanium dioxide
- gelatin

In addition, the 16 mg capsules contain:

- iron oxide red

In addition, the 24 mg capsules contain:

- indigo carmine
- erythrosine
- iron oxide red
- iron oxide yellow.

This medicine does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes. It contains traces of galactose. May contain traces of sulfites.

Sponsor

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