

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

Read this leaflet carefully before taking your medicine.

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

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want 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 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.

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.

How it works

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

There is no evidence that this medicine is addictive.

Use in children

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 or have had any of the following:**
 - severe liver disease
 - severe kidney disease.
- **You are hypersensitive to, or have had an allergic reaction to, galantamine or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: 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; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - liver and/or kidney disease
 - heart problems
 - stomach ulcers
 - brain disorders, such as Parkinson's disease, fits (seizures)
 - breathing disorders, such as asthma, pneumonia
 - recent gut or bladder surgery
 - difficulties in passing urine
 - attacks of sudden abdominal pain.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
5. You are planning to have surgery or an anaesthetic.
6. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available 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. bethanecol and certain medicines used during surgery)
- medicines used to treat Parkinson's disease
- medicines for certain heart problems (such as digoxin, quinidine) or to help lower blood pressure (such as a class of medicine called beta blockers)

- medicines used for breathing problems
- certain medicines used to treat fungal infections (such as ketoconazole) or bacterial infections (such as erythromycin)
- certain medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- certain medicines used to treat depression (such as paroxetine, fluoxetine, fluvoxamine).

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with galantamine.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

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.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

The dose of APO-Galantamine MR 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.

The capsule must be swallowed whole. The contents should not be crushed and sprinkled on food.

Be sure to drink plenty of liquids during your treatment with APO-Galantamine MR to keep yourself hydrated.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It is preferable to take this medicine with food.

How long to take it for

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

Make sure you have enough to last over weekends and holidays.

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 at the usual time. 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 have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

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

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

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

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

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

Weight loss is associated with this medicine and is common for people with Alzheimer's. Therefore, you and your doctor should monitor your weight while taking this medication.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking galantamine or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- nausea, vomiting, diarrhoea, stomach pain or discomfort, indigestion
- tiredness, weakness
- muscle cramps, trembling, numbness and tingling or burning sensation
- headache
- ringing in the ears
- dehydration (sometimes severe) - thirst, lack of fluids
- hallucinations (seeing, feeling or hearing things that are not there)
- feeling depressed or having thoughts of harming yourself
- dizziness, light-headedness
- slow, fast or irregular heart beat
- increased sweating
- changes in taste
- loss of appetite, weight loss
- fainting or falling (sometimes resulting in injury)
- high blood pressure
- abnormal liver test results

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- yellowing of the skin and eyes
- light coloured bowel motions, 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
- flu-like symptoms with a red, pustule rash

- 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.

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

Allergic reactions

If you think you are having an allergic reaction to galantamine, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- 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
- fainting
- hay fever-like symptoms.

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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

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.
- **16 mg modified release capsules**
Flesh opaque capsules containing two round biconvex tablets.
- **24 mg modified release capsules**
Orange opaque capsules containing three round biconvex tablets.

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

Ingredients

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

It also contains the following inactive ingredients:

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

In addition, the 16 mg capsules contain:

- iron oxide red

And the 24 mg capsules contain:

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

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

- APO-Galantamine MR 8 mg capsules (blister packs): AUST R 182030.
- APO-Galantamine MR 16 mg capsules (blister packs): AUST R 182041.
- APO-Galantamine MR 24 mg capsules (blister packs): AUST R 182034.

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

APO and APOTEX are registered trade marks of Apotex Inc.

This leaflet was last updated in March 2015.