

GALANTYL™

Modified Release Capsules

contains the active ingredient galantamine (as hydrobromide)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about GALANTYL extended release capsules.

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 GALANTYL against the benefits this medicine is expected to have for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What GALANTYL is used for

GALANTYL 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. GALANTYL increases the amount of this substance to help improve or stabilise the symptoms

and therefore slow the progress of Alzheimer's disease.

Your doctor may have prescribed GALANTYL for another reason.

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

Your doctor may have prescribed it for another reason.

It is available only with a doctor's prescription.

Before you take GALANTYL

When you must not take it

Do not take GALANTYL if you have:

- an allergy to any medicine containing galantamine
- an allergy to any of the ingredients listed at the end of this leaflet
- severe liver and/or kidney disease.

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 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.

Before you start to take it

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

You must tell your doctor if you are:

- pregnant, or planning to become pregnant
- breastfeeding, or planning to breastfeed
- planning to undergo surgery which will require anaesthesia.

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, fits
- breathing disorders, such as asthma, pneumonia
- recent gut or bladder surgery
- difficulties in passing urine
- attacks of sudden abdominal pain.

If you have not told your doctor or pharmacist about any of the above, tell him/her before you start taking GALANTYL.

Your doctor will advise you whether or not to take GALANTYL or if you need to adjust the dose or alter your treatment. Since there may be other related conditions that GALANTYL is not intended to treat, you should verify with your doctor that you are taking GALANTYL for the treatment

of mild to moderate Alzheimer's disease.

Initial results from clinical trials in patients with mild cognitive impairment of various causes have shown a slightly higher mortality rate (higher death rate) in those taking GALANTYL than those taking placebo (a pill without an active ingredient which is commonly used in clinical trials as a reference for comparison). The reason for this difference is currently not known and may just be due to chance. There is no evidence of increased risk of death in those with mild to moderately severe Alzheimer's disease taking GALANTYL.

Taking other medicines

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

In particular, tell your doctor or pharmacist if you are taking any of the following:

- 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).

These medicines may be affected by GALANTYL or may affect how well GALANTYL 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.

How to take GALANTYL

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Adults

The dose of GALANTYL 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.

If treatment is discontinued for more than several days, tell your doctor. Your doctor will need to re-start your treatment at the lowest dose. This

will minimise the chance of experiencing side effects.

Children

GALANTYL is not recommended for children.

If you do not understand the instructions provided with this medicine, ask your doctor or pharmacist for help.

How to take it

Take your medicine at about the same time each day.

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

GALANTYL modified release capsules should be taken once a day, preferably with food. Be sure to drink plenty of liquids during your treatment with GALANTYL to keep yourself hydrated.

How long to take it

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

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

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

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

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you have missed more than one dose, or are not sure what to do, check with your doctor or pharmacist.

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

If you have taken too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much GALANTYL. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Poisons Information Centre telephone numbers:

- **Australia: 13 11 26**
- **New Zealand: 0800 764 766 or 0800 POISON**

Keep these telephone numbers handy.

If you take too much GALANTYL, you may experience vomiting or a feeling that you want to vomit, nausea, stomach cramps, excessive production of saliva, tears or sweat, dry mouth, loss of control of your bladder or bowels, a slow or fast heart beat, low blood pressure, dizziness, light-headedness, muscle weakness or twitching, fits, breathing difficulties, chest pain, hallucinations or you may collapse.

While you are taking GALANTYL

Things you must do

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

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.

If you become pregnant while taking this medicine, tell your doctor immediately.

Things you must not do

Do not take GALANTYL 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 change the dosage without checking with your doctor.

Things to be careful of

Effects on driving and operating machinery

- Alzheimer's disease may reduce your ability to drive or operate machines.
- GALANTYL may cause dizziness or drowsiness in some people, especially during initial treatment.
- Discuss with your doctor whether it is safe for you to drive or operate machinery.

Side Effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects.

Do not be alarmed by this list of possible 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 experience any of the following and they worry you:

- nausea, vomiting, diarrhoea, stomach pain or discomfort, indigestion, difficulty swallowing
- low potassium levels in the blood - weakness, muscle cramps,

numbness and tingling that begins in the lower extremities.

- leg cramps, tingling in the hands or feet
- ringing in the ears
- dehydration (sometimes severe) - thirst, lack of fluids
- hallucinations (seeing, feeling or hearing things that are not there)
- mood changes such as agitation or aggressive feelings
- feeling depressed or having thoughts of harming yourself
- low blood pressure - dizziness, light-headedness
- slow, fast or irregular heart beat
- increased sweating
- fever
- skin rashes
- trembling or shakiness
- loss of appetite, weight loss
- drowsiness, tiredness, weakness, feeling unwell, confusion, trouble sleeping, headache
- falling (sometimes resulting in injury)
- runny or blocked nose
- urinary tract infection.
- high blood pressure
- elevated liver enzymes
- yellowing of the skin and eyes
- light coloured bowel motions
- dark coloured urine.

Some of these side effects occur mainly during the early stages of treatment, or when the dose of GALANTYL is increased. They usually disappear gradually over time. For example, nausea and vomiting tend to pass after a few days.

Some of these effects may be due to the Alzheimer's disease but always inform your doctor about any unwanted effect that has occurred while taking GALANTYL.

Tell your doctor immediately, or go to Accident and Emergency at

your nearest hospital if you notice any of the following:

- signs of allergy such as rash or hives on the skin; swelling of the face, lips, tongue or other parts of the body; wheezing or difficulty breathing.
- 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
- 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

These may be serious side effects. You may need urgent medical attention. These are rare side effects. Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

After taking GALANTYL

Storage

Keep your capsules in the pack until it is time to take them.

If you take the capsules out of the pack they may not keep well.

Keep your capsules in a cool dry place where the temperature stays below 25°C.

Do not store GALANTYL 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 your medicines where children cannot reach them.

A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking GALANTYL or your medicine has passed its expiry date, ask your pharmacist what to do with any medicine which may be left over.

Product description

What it looks like

There are 3 different types of GALANTYL extended release capsules. Each capsule contains a different amount of the active ingredient.

- GALANTYL 8 mg extended release capsule are size 2, hard gelatin capsule with a white body and pink cap printed in black ink "MYLAN" over "GT 8" on both the body and the cap.
- GALANTYL 16 mg extended release capsule are size 2, hard gelatin capsule with a white body and pale pink cap printed in black ink "MYLAN" over "GT 16" on both the body and the cap.
- GALANTYL 24 mg extended release capsules are size 1, hard gelatin capsule with a white body and pink cap printed in black ink "MYLAN" over "GT 24" on both the body and the cap.

All strengths are available in blister packs of 28 extended release capsules.

Ingredients

The active ingredient of GALANTYL is galantamine (as hydrobromide).

GALANTYL extended release capsules contain either 8 mg, 16mg or 24 mg of galantamine.

All capsules also contain Kollidon® SR, Povidone, Vegetable Oil-Hydrogenated, and Magnesium Stearate in a hard gelatin capsule.

In addition, the 8mg, 16 mg and 24 mg capsules contain Allura Red AC (E129).

GALANTYL extended release capsules do not contain gluten.

Manufacturer/Supplier

GALANTYL is made by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

The Australian Registration Numbers are:

GALANTYL 8 mg capsules (Blister Pack): AUST R 157934.

GALANTYL 16 mg capsules (Blister Pack): AUST R 157932.

GALANTYL 24 mg capsules (Blister Pack): AUST R 157933.

This leaflet was prepared on 27 May 2010.