

# GALANTYL®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

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### 1. Why am I taking GALANTYL?

GALANTYL contains the active ingredient galantamine (as hydrobromide). GALANTYL is used to treat mild to moderately severe dementia of the Alzheimer's type. For more information, see Section [1. Why am I taking GALANTYL?](#) in the full CMI.

### 2. What should I know before I take GALANTYL?

Do not take if you have ever had an allergic reaction to any medicine containing galantamine or any of the ingredients listed at the end of the CMI or have severe liver and/or kidney disease.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I take GALANTYL?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with GALANTYL and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I take GALANTYL?

GALANTYL should be taken at least once daily, preferably with food. Be sure to drink plenty of liquids during your treatment with GALANTYL to keep yourself hydrated. Follow dosage directions given to you by your doctor or pharmacist and continue taking it for as long as your doctor tells you.

- More instructions can be found in Section [4. How do I take GALANTYL?](#) in the full CMI.

### 5. What should I know while taking GALANTYL?

| Things you should do |                                                                                                                                    |
|----------------------|------------------------------------------------------------------------------------------------------------------------------------|
|                      | <ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking GALANTYL.</li></ul> |

|                                  |                                                                                                                                                                                                                                                                                                                                    |
|----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                  | <ul style="list-style-type: none"> <li>• Always follow your doctor's instructions carefully.</li> <li>• Tell your doctor if you become pregnant while taking GALANTYL.</li> <li>• Tell your doctor if you develop a rash or fever.</li> </ul>                                                                                      |
| <b>Things you should not do</b>  | <ul style="list-style-type: none"> <li>• Do not take GALANTYL to treat any other complaint unless your doctor says so.</li> <li>• Do not give GALANTYL to anyone else, even if they have the same condition as you.</li> <li>• Do not stop taking your medicine or change the dosage without checking with your doctor.</li> </ul> |
| <b>Driving or using machines</b> | <ul style="list-style-type: none"> <li>• GALANTYL may cause dizziness or drowsiness in some people, especially during initial treatment.</li> <li>• Alzheimer's disease may reduce your ability to drive or operate machines.</li> </ul>                                                                                           |

|                                    |                                                                                                                                                                                                |
|------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                    | <ul style="list-style-type: none"> <li>• Discuss with your doctor whether it is safe for you to drive or operate machinery.</li> </ul>                                                         |
| <b>Looking after your medicine</b> | <ul style="list-style-type: none"> <li>• Keep GALANTYL in the pack until it is time to take them.</li> <li>• Keep GALANTYL in a cool dry place where the temperature is below 25°C.</li> </ul> |

For more information, see Section [5. What should I know while taking GALANTYL?](#) in the full CMI.

## 6. Are there any side effects?

Common side effects include nausea, vomiting, diarrhoea, stomach pain, indigestion, decreased appetite, dizziness, headache, tremors, fainting, fatigue, drowsiness, depression, fast heartbeat, muscle spasms, loss of strength, feeling ill, weight loss.

More serious side effects include signs of allergy (rash or hives on the skin, swelling of the face, lips, tongue or other parts of the body, and wheezing or difficulty breathing), vomiting blood, bloody diarrhoea, seizures, chest tightness or pain, 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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# **GALANTYL®**

**Active ingredient(s):** *Galantamine (as hydrobromide)*

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## **Consumer Medicine Information (CMI)**

This leaflet provides important information about taking GALANTYL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking GALANTYL.**

**Where to find information in this leaflet:**

- [1. Why am I taking GALANTYL?](#)
- [2. What should I know before I take GALANTYL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take GALANTYL?](#)
- [5. What should I know while taking GALANTYL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## **1. Why am I taking GALANTYL?**

**GALANTYL contains the active ingredient galantamine (as hydrobromide).**

**GALANTYL is used to treat mild to moderately severe dementia of the Alzheimer type.**

The symptoms of Alzheimer's disease include confusion, memory loss, or other changes in behaviour. As the disease progresses, patients find it 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 acetylcholine 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.

## **2. What should I know before I take GALANTYL?**

### **Warnings**

#### **Do not take GALANTYL if:**

- you are allergic to any medicine containing galantamine (as hydrobromide), or 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

Always check the ingredients to make sure you can take this medicine

- you have severe liver and/or kidney disease
- the expiry date printed on the pack has passed or if the package is torn or shows signs of tampering.

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

### **Tell your doctor if you are:**

- allergic to any other medicines, foods, preservatives or dyes
- pregnant, or planning to become pregnant
- breastfeeding, or planning to breastfeed
- planning to undergo surgery which will require anaesthesia.

### **Check with 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
- problems controlling movements of the body or limbs (extrapyramidal disorders)
- breathing disorders such as asthma or pneumonia
- recent gut or bladder surgery
- difficulties passing urine



- attacks of sudden abdominal pain
- low potassium levels in the blood which may be causing weakness, muscle cramps, numbness and tingling that begins in the lower extremities

**If you have not told your doctor or pharmacist about any of the above, tell them 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 impairments of various causes have shown a slightly 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

## **Children**

- GALANTYL is not recommended for children.

### **3. What if I am taking other medicines?**

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

**Some medicines may interfere with GALANTYL and affect how it works. 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 (such as digoxin or 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, obsessive compulsive disorder (OCD), panic disorder or anxiety (such as paroxetine, fluoxetine, or fluvoxamine).

You may need different amounts of your medicines, or you may need to take different medicines.

**Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.**

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect GALANTYL.**

## **4. How do I 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 if that dose 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.

### How to take it

GALANTYL modified release capsules should be taken once a day in the morning, preferably with food.

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

The capsule must be swallowed whole. The contents should not be crushed or sprinkled in food.

## **When to take GALANTYL**

GALANTYL should be taken at the same time each day in the morning.

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

## **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 GALANTYL**

**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 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 take too much GALANTYL**

If you think that you or anyone else may have taken too much GALANTYL, urgent medical attention may be needed.

### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

### **You should do this even if there are no signs of discomfort or poisoning.**

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

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

## **5. What should I know while taking GALANTYL?**

### **Things you should do**

- Always follow your doctor's instructions carefully.
- If you are about to start taking a new medicine, remind your doctor or pharmacist that you are taking GALANTYL.
- Tell your doctor if you develop a rash or fever.
- Tell your doctor immediately if you become pregnant while taking GALANTYL.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.
- Remind any doctor, dentist or pharmacist you visit that you are taking GALANTYL.

### **Things you should not do**

- Do not take GALANTYL to treat any other complaint unless your doctor tells you to.
- Do not give GALANTYL 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.

## **Driving or using machines**

Discuss with your doctor whether it is safe for you to drive or operate machinery while taking GALANTYL.

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

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

## **Looking after your medicine**

- 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 is below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

## **Keep it where young children cannot reach it.**

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



## How to discard your medicine

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.

### 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

#### Less serious side effects

| Less serious side effects                                                                                                                                                        | What to do                                                                                         |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| <b>General disorders:</b> <ul style="list-style-type: none"><li>• Feeling unwell</li><li>• Increased sweating</li><li>• Skin rashes</li></ul> <b>Gastrointestinal disorders:</b> | <b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b> |

| Less serious side effects                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | What to do |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| <ul style="list-style-type: none"> <li>• Nausea, vomiting</li> <li>• Diarrhoea</li> <li>• Stomach pain or discomfort, indigestion</li> <li>• Difficulty swallowing</li> <li>• Loss of appetite, weight loss</li> <li>• Light coloured bowel motions</li> </ul> <p><b>Ear disorders:</b></p> <ul style="list-style-type: none"> <li>• Ringing in the ears</li> </ul> <p><b>Eye disorders:</b></p> <ul style="list-style-type: none"> <li>• Blurred vision</li> </ul> <p><b>Nervous system disorders:</b></p> <ul style="list-style-type: none"> <li>• Distorted sense of taste</li> <li>• Muscle spasm/cramps including leg cramps, numbness and tingling that begins in the lower extremities (hands or feet)</li> <li>• Hallucinations (seeing, feeling, or hearing things that are not there)</li> <li>• Drowsiness, tiredness, weakness, headache</li> </ul> |            |

| Less serious side effects                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | What to do |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| <ul style="list-style-type: none"> <li>• Trembling or shaking</li> <li>• Falling (sometimes resulting in injury)</li> <li>• Problem controlling movements of the body or limbs (extrapyramidal disorder)</li> </ul> <p><b>Psychiatric disorders:</b></p> <ul style="list-style-type: none"> <li>• Feeling depressed or having thoughts of harming yourself</li> <li>• Mood changes such as agitation or aggressive feelings</li> <li>• Confusion</li> <li>• Trouble sleeping</li> </ul> <p><b>Cardiovascular disorders:</b></p> <ul style="list-style-type: none"> <li>• Low blood pressure<br/>- dizziness, light-headedness</li> <li>• Slow, fast, or irregular heartbeat</li> <li>• High blood pressure</li> </ul> <p><b>Kidney or Urinary disorders:</b></p> |            |

| <b>Less serious side effects</b>                                                                                                                                                                                                                                                               | <b>What to do</b> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| <ul style="list-style-type: none"> <li>• Dehydration (sometimes severe) - thirst, lack of fluids</li> <li>• Dark coloured urine</li> </ul> <p><b>Liver disorders:</b></p> <ul style="list-style-type: none"> <li>• Yellowing of the skin and eyes</li> <li>• Elevated liver enzymes</li> </ul> |                   |

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

## **Serious side effects**

| <b>Serious side effects</b>                                                                                                                                                                           | <b>What to do</b>                                                                                                        |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| <p><b>Allergy related:</b></p> <ul style="list-style-type: none"> <li>• Signs of allergy such as rash or hives on the skin; swelling of the face, lips, tongue or other parts of the body;</li> </ul> | <p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you</b></p> |

| Serious side effects                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | What to do                                              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|
| <p>wheezing or difficulty breathing</p> <p><b>Gastrointestinal disorders:</b></p> <ul style="list-style-type: none"> <li>• Vomiting blood or material that looks like coffee grounds</li> <li>• Bleeding from the back passage, black sticky bowel motions (stools), or bloody diarrhoea</li> <li>•</li> </ul> <p><b>Nervous system disorders:</b></p> <ul style="list-style-type: none"> <li>• Fits (seizures)</li> </ul> <p><b>Cardiovascular disorders:</b></p> <ul style="list-style-type: none"> <li>• Fainting, especially if you have a slow or irregular heartbeat</li> <li>• Pain or tightness in the chest</li> <li>• symptoms of stroke which can include collapsing, numbness or weakness of arms or legs, headache, dizziness and confusion, visual disturbance,</li> </ul> | <p><b>notice any of these serious side effects.</b></p> |

| Serious side effects                                                                                                                                                                                                                                                                                                                                                                           | What to do |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| <p>difficulty swallowing, slurred speech and loss of speech</p> <p><b>Skin disorders:</b></p> <ul style="list-style-type: none"> <li>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 generalised exanthematous pustulosis)</li> </ul> |            |

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side

effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What GALANTYL contains

|                                                     |                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Active ingredient<br/>(main ingredient)</b>      | Galantamine (as hydrobromide)                                                                                                                                                                                                                                                                                                                                                                |
| <b>Other ingredients<br/>(inactive ingredients)</b> | <ul style="list-style-type: none"><li>• Kollidon Sr (ID: 106078)</li><li>• Povidone</li><li>• Hydrogenated Vegetable Oil</li><li>• Magnesium Stearate</li><li>• 8 mg: Empty Gelatin Capsule RM 991 Size 2 White op body - Pink op cap with Mylan and GT8 in Black Ink (ID: 105899)</li><li>• 16 mg: Empty Gelatin Capsule RM 992 Size 2 White op body - Pink op cap with Mylan and</li></ul> |

|                            |                                                                                                                                                                                                            |
|----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                            | GT16 in Black Ink (ID: 105900)<br><ul style="list-style-type: none"> <li>• 24 mg: Empty Gelatin Capsule RM 993 Size 1 White op body - Pink op cap with Mylan and GT24 in Black Ink (ID: 105898)</li> </ul> |
| <b>Potential allergens</b> | traces of sulfites                                                                                                                                                                                         |

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

**Do not take this medicine if you are allergic to any of these ingredients.**

## What GALANTYL looks like

- **GALANTYL 8 mg** modified 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. (AUST R 157934).
- **GALANTYL 16 mg** modified 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. (AUST R 157932).
- **GALANTYL 24 mg** modified 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. (AUST R 157933).



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

## **Who distributes GALANTYL**

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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GALANTYL® is a Viatris company trade mark

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