REMINYL®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using REMINYL?

REMINYL contains the active ingredient galantamine (as hydrobromide). REMINYL is used to treat mild to moderately severe dementia of the Alzheimer's type.

For more information, see Section 1. Why am I using REMINYL? in the full CMI.

2. What should I know before I use REMINYL?

Do not use REMINYL 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 use REMINYL? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with REMINYL 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 use REMINYL?

REMINYL should be taken at least once daily, preferably with food. Be sure to drink plenty of liquids during your treatment with REMINYL 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 use REMINYL? in the full CMI.

5. What should I know while using REMINYL?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using REMINYL. • Always follow your doctor's instructions carefully. • Tell your doctor if you become pregnant while taking REMINYL. • Tell your doctor if you develop a rash or fever.
Things you should not do	• Do not use REMINYL to treat any other complaint unless your doctor says so. • Do not give REMINYL to anyone else, even if their symptoms seem similar to yours.
Driving or using machines	• REMINYL may cause dizziness or drowsiness in some people, especially during initial treatment. • Alzheimer's disease may reduce your ability to drive or operate machines. • Discuss with your doctor whether it is safe for you to drive or operate machinery.
Looking after your medicine	• Keep REMINYL in the pack until it is time to take them. • Keep REMINYL in a cool dry place where the temperature is below 30°C.

For more information, see Section 5. What should I know while using REMINYL? 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.

REMINYL®

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

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

1. Why am I using REMINYL?
2. What should I know before I use REMINYL?
3. What if I am taking other medicines?
4. How do I use REMINYL?
5. What should I know while using REMINYL?
6. Are there any side effects?
7. Product details

1. Why am I using REMINYL?

REMINYL contains the active ingredient galantamine (as hydrobromide).

REMINYL 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 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. REMINYL 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 REMINYL 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 use REMINYL?

Warnings

Always check the ingredients to make sure you can use this medicine.

Do not use REMINYL if:

- you are allergic to Galantamine (as hydrobromide), or any of the ingredients listed at the end of this leaflet.
- you have severe liver and/or kidney disease.
- the package is torn or shows signs of tampering.

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 seizures
- 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

Initial results from clinical trials in patients with mild cognitive impairments of various causes have shown a slightly higher death rate in those taking REMINYL 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 REMINYL.

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

REMINYL 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 medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with REMINYL and affect how it works. These medicines 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).

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 REMINYL.

4. How do I use REMINYL?

How much to take

REMINYL should be taken at least once daily, preferably with food. Be sure to drink plenty of liquids during your treatment with REMINYL to keep yourself hydrated. The capsule must be swallowed whole. The contents should not be crushed or sprinkled in food.

Adults

The dose of REMINYL 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.

Follow the instructions provided and use REMINYL until your doctor tells you to stop.

Children

REMINYL is not recommended for children.

When to take REMINYL

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

If you forget to use REMINYL

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.

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 use too much REMINYL

If you think that you have used too much REMINYL, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26 in Australia OR 0800 764 766 or 0800 POISON in New Zealand**), 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.

Symptoms of taking too much REMINYL may include nausea, vomiting, stomach cramps, excessive production of saliva, tears or sweat, dry mouth, loss of control of 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.

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

5. What should I know while using REMINYL?

Things you should do

- **Always follow your doctor's instructions carefully.**
- **If you are about to start taking a new medicine, tell your doctor or pharmacist that you are taking REMINYL.**
- **Tell your doctor if you develop a rash or fever.**
- **Tell your doctor if you become pregnant while taking REMINYL.**

Call your doctor straight away if you:

- experience any of the serious side effects listed under Section 6. Are there any side effects.

Remind any doctor, dentist or pharmacist you visit that you are using REMINYL.

Things you should not do

- Do not use REMINYL to treat any other complaint unless your doctor says so.
- Do not give REMINYL to anyone else, even if their symptoms seem similar to yours.

Driving or using machines

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

REMINYL may cause dizziness in some people, especially during initial treatment.

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

Looking after your medicine

- Keep REMINYL in the pack until it is time to take them.
- Keep REMINYL in a cool dry place where the temperature is below 30°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.

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 REMINYL, 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.

Less serious side effects

Less serious side effects	What to do
General disorders: • Feeling unwell • Increased sweating **Gastrointestinal disorders:** • Nausea, vomiting • Diarrhoea • Stomach pain or discomfort, indigestion • Difficulty swallowing • Loss of appetite, weight loss • Light coloured bowel motions **Ear disorders:** • Ringing in the ears **Eye disorders:** • Blurred vision **Nervous system disorders:** • Distorted sense of taste • Muscle spasm, tingling in the hands or feet • Hallucinations (seeing, feeling, or hearing things that are not there)	**Speak to your doctor if you have any of these less serious side effects and they worry you.**
• Drowsiness, tiredness, weakness, headache • Trembling or shaking • Falling (sometimes resulting in injury) • Problem controlling movements of the body or limbs (extrapyramidal disorder) **Psychiatric disorders:** • Feeling depressed or having thoughts of harming yourself • Nightmare **Cardiovascular disorders:** • Low blood pressure - dizziness, light-headedness • Slow, fast, or irregular heart beat • High blood pressure **Kidney or Urinary disorders:** • Dehydration (sometimes severe) - thirst, lack of fluids • Dark coloured urine **Liver disorders:** • Yellowing of the skin and eyes Some of these less serious side effects occur mainly during the early stages of treatment, or when the dose of REMINYL 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 REMINYL.	

Serious side effects

Serious side effects	What to do
Allergy related: • 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 **Gastrointestinal disorders:** • Vomiting blood or material that looks like ground coffee • Bleed from the back passage, black sticky bowel motions (stools), or bloody diarrhoea	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
Nervous system disorders: • Fits (seizures) **Cardiovascular disorders:** • Fainting, especially if you have a slow or irregular heart bear • Pain or tightness in the chest **Skin disorders:** • 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)	

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. 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 REMINYL contains

Active ingredient (main ingredient)	Galantamine (as hydrobromide)
Other ingredients (inactive ingredients)	Capsule pellets: • diethyl phthalate • ethylcellulose • hypromellose • non-pareil beads / sugar spheres (contains sucrose) • Opadry clear OY-7240 (PI 3234) Capsule shell: • 8 mg: empty hard gelatin capsules size 4 white Op. 44.000/44.000 pure bovine (ARTG PI No 108031) • 16 mg: Empty hard gelatin capsules size 2 37.024 Flesh Op.C024 pure bovine (ARTG PI No 108029) • 24 mg: Empty hard gelatin capsules size 1 36.092 Caramel Op.C024 pure bovine (ARTG PI No 108030) • iron oxide red (16 mg and 24 mg capsules only) • iron oxide yellow (24 mg capsule only) • titanium dioxide Printing ink: • Opacode monogramming ink S-1-277002 Black (PI 107581) or • TekPrint SW-9008 Black Ink (PI 2328) • Both inks contain shellac, iron oxide black and propylene glycol

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

What REMINYL looks like

REMINYL modified release capsules are available in blister pack of 28 capsules:

- **8 mg modified release capsules (AUST R 97883):** White opaque capsules marked with 'G8', containing white to off-white pellets.
- **16 mg modified release capsules (AUST R 97885):** Pink opaque capsules marked with 'G16', containing white to off-white pellets.
- **24 mg modified release capsules (AUST R 97887):** Caramel opaque capsules marked with 'G24', containing white to off-white pellets.

Who distributes REMINYL

Australia

Clinect Pty Ltd

120-132 Atlantic Drive

Keysborough VIC 3173

Telephone: 1800 899 005

New Zealand

Clinect NZ Pty Limited

C/- Ebos Group Limited

108 Wrights Road

Christchurch 8024

Telephone: 0800 138 803

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