

REMINYL®

Prolonged Release Capsules

Galantamine hydrobromide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about REMINYL prolonged 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 REMINYL against the benefits this medicine is expected to have for you.

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

Keep this leaflet with your medicine. You may need to read it again.

What REMINYL is used for

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

Before you take REMINYL

When you must not take it

Do not take REMINYL if you have:

- an allergy to REMINYL or any of the ingredients. See Product Description at the end of this leaflet for a list of ingredients.
- severe liver and/or kidney disease.

Do not take REMINYL if the packaging is torn or shows signs of tampering. Do not use REMINYL beyond the expiry date (month and year) printed on the pack.

Before you start to take it

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.

You must also tell your doctor if you have, or have had any of the following health problems:

- 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 them before you start taking or are given REMINYL.

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

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 REMINYL or may affect how well REMINYL works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

Effects on driving and operating machinery

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

Taking REMINYL

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

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 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

REMINYL is not recommended for children.

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

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 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 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.

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 REMINYL, 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 REMINYL

Things you must do

- Always follow your doctor's instructions carefully.

- Tell your doctor if you become pregnant while taking REMINYL.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking REMINYL.

Things you must not do

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

Side Effects

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 REMINYL 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 REMINYL.

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 REMINYL

Storage

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.

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.

Do not store REMINYL, or any other medicine, in the bathroom or near a sink. Do not leave medicines in the car or on windowsills. Heat and dampness can destroy some medicines.

Disposal

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.

Product Description

What it looks like

There are 3 different types of REMINYL prolonged release capsules. Each capsule contains a

different amount of the active ingredient.

- **REMINYL 8 mg prolonged release capsules**

White opaque capsules marked with 'G8', containing white to off-white pellets.

- **REMINYL 16 mg prolonged release capsules**

Pink opaque capsules marked with 'G16', containing white to off-white pellets.

- **REMINYL 24 mg prolonged release capsules**

Caramel opaque capsules marked with 'G24', containing white to off-white pellets.

Reminyl prolonged release capsules are available in blister pack of 28 capsules or bottles of 30 capsules.

Ingredients

The active ingredient of REMINYL is galantamine hydrobromide.

REMINYL prolonged release capsules contain either 8 mg, 16mg or 24 mg of galantamine.

All capsules also contain opadry clear OY-7240, non-pareil beads, diethyl phthalate, ethylcellulose, hypromellose in a hard gelatin capsule.

In addition, the 16 mg and 24 mg capsules contain red ferric oxide (172) and the 24 mg capsule also contains yellow ferric oxide (172).

REMINYL prolonged release capsules do not contain gluten.

Sponsor

JANSSEN-CILAG Pty Ltd

1-5 Khartoum Road North Ryde
NSW 2113

Australia

Telephone: (02) 8875 3333

NZ Office: Auckland New Zealand

Telephone: 0800 800 806

The Australian Registration Numbers are:

REMINYL 8 mg capsules -

AUST R 97883 and AUST R 97882

REMINYL 16 mg capsules -

AUST R 97885 and AUST R 97884

REMINYL 24 mg capsules -

AUST R 97887 and AUST R 97886

This leaflet was prepared in June 2010.