Package leaflet: Information for the user

Reminyl 8 mg prolonged-release capsules, hard
Reminyl 16 mg prolonged-release capsules, hard
Reminyl 24 mg prolonged-release capsules, hard

galantamine

Read all of this leaflet carefully before you start taking this medicine because if contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Reminyl is and what it is used for
2. What you need to know before you take Reminyl
3. How to take Reminyl
4. Possible side effects
5. How to store Reminyl
6. Contents of the pack and other information.

1. What Reminyl is and what it is used for

Reminyl contains the active substance ‘galantamine’, an antidementia medicine. It is used in adults to treat the symptoms of mild to moderately severe Alzheimer’s disease, a type of dementia that alters brain function.

Alzheimer’s disease causes increasing memory loss, confusion and behavioural changes, which make it increasingly difficult to carry out normal daily activities. These effects are thought to be caused by a lack of ‘acetylcholine’, a substance responsible for sending messages between brain cells. Reminyl increases the amount of acetylcholine in the brain and treats the signs of the disease.

The capsules are made in a ‘prolonged-release’ form. This means that they release the medicine slowly.

2. What you need to know before you take Reminyl

Do not take Reminyl
- if you are allergic to galantamine or to any of the other ingredients of this medicine (listed in section 6).
- if you have severe liver or severe kidney disease.

Warnings and precautions
Talk to your doctor or pharmacist before taking Reminyl. This medicine is only used in Alzheimer’s disease, and is not recommended for other types of memory loss or confusion.

Serious side effects
Reminyl can cause serious skin reactions, heart problems and fits (seizures). You must be aware of these side effects while you are taking Reminyl. See ‘Look out for serious side effects’ in section 4.

Before you take Reminyl, your doctor needs to know if you have, or have had, any of the following:
- liver or kidney problems
- a heart condition (such as chest discomfort that is often brought on by physical activity, a heart attack, heart failure, slow or uneven heart beat, prolonged QTc interval)
- changes in 'electrolyte' levels (naturally occurring chemicals in the blood, such as potassium)
- a peptic (stomach) ulcer
- blockage of the stomach or intestines
- a disorder of the nervous system [such as epilepsy or problems controlling movements of the body or limbs (extrapyramidal disorder)]
- a respiratory disease or infection that affects breathing (such as asthma, obstructive pulmonary disease or pneumonia)
- problems passing urine.

Your doctor will decide if Reminyl is suitable for you, or if the dose needs to be changed.

Also tell your doctor if you recently had an operation on the stomach, intestines or bladder. Your doctor may decide that Reminyl is not suitable for you.

Reminyl can cause weight loss. Your doctor will check your weight regularly while you are taking Reminyl.

Children and adolescents
Reminyl is not recommended for children and adolescents.

Other medicines and Reminyl
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Reminyl should not be used with medicines that work in a similar way. These include:
- donepezil or rivastigmine (for Alzheimer's disease)
- ambenonium, neostigmine or pyridostigmine (for severe muscle weakness)
- pilocarpine (when taken by mouth for dry mouth or dry eyes).

Some medicines can make side effects more likely in people taking Reminyl. These include:
- medicines affecting the QTc interval
- paroxetine or fluoxetine (antidepressants)
- quinidine (for uneven heart beat)
- ketoconazole (an antifungal)
- erythromycin (an antibiotic)
- ritonavir (for human immunodeficiency virus or 'HIV')
- non-steroidal anti-inflammatory painkillers (such as ibuprofen), which can increase the risk of ulcers
- medicines taken for heart conditions or high blood pressure (such as digoxin, amiodarone, atropine, beta-blockers, or calcium channel blocking agents). If you take medicines for an uneven heart beat, your doctor may check your heart using an 'electrocardiogram' (ECG).

Your doctor may give you a lower dose of Reminyl if you are taking some of these medicines.

Reminyl may affect some anaesthetics. If you are going to have an operation under a general anaesthetic, tell the doctor that you are taking Reminyl, well in advance.

If you have any questions, talk to your doctor or pharmacist for advice.

Pregnancy and breast-feeding
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not breast-feed while you are taking Reminyl.

Driving and using machines
Reminyl may make you feel dizzy or sleepy, especially during the first few weeks of treatment. If Reminyl affects you, do not drive or use any tools or machinery.

Reminyl contains sucrose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Reminyl capsules

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If you are currently taking Reminyl tablets or oral solution and have been told by your doctor to switch to Reminyl prolonged-release capsules, carefully read the instructions under 'Switching from taking Reminyl tablets or oral solution to Reminyl capsules' in this section.

How much to take
You will start treatment with Reminyl at a low dose. The usual starting dose is 8 mg, taken once a day. Your doctor may gradually increase your dose, every 4 weeks or more, until you reach a dose that is suitable for you. The maximum dose is 24 mg, taken once a day.

Your doctor will explain what dose to start with and when the dose should be increased. If you are not sure what to do, or find the effect of Reminyl is too strong or too weak, talk to your doctor or pharmacist.

Your doctor will need to see you regularly, to check that this medicine is working and to discuss how you are feeling.

If you have liver or kidney problems, your doctor may give you a reduced dose of Reminyl, or may decide this medicine is not suitable for you.

Switching from taking Reminyl tablets or oral solution to Reminyl capsules
If you are currently taking Reminyl tablets or oral solution, your doctor may decide you should switch to Reminyl prolonged-release capsules. If this applies to you:
- Take your last dose of Reminyl tablets or oral solution in the evening
- The next morning, take your first dose of Reminyl prolonged-release capsules.

DO NOT take more than one capsule in a day. While you are taking once-daily Reminyl capsules, DO NOT take Reminyl tablets or oral solution.

How to take
Reminyl capsules must be swallowed whole and NOT chewed or crushed. Take your dose of Reminyl once a day in the morning, with water or other liquids. Try to take Reminyl with food.

Drink plenty of liquids while you are taking Reminyl, to keep yourself hydrated.

If you take more Reminyl than you should
If you take too much Reminyl, contact a doctor or hospital straight away. Take any remaining capsules and the packaging with you. The signs of overdose may include:
- severe nausea and vomiting
- weak muscles, slow heart beat, fits (seizures) and loss of consciousness.

If you forget to take Reminyl
If you forget to take one dose, miss out the forgotten dose completely and take the next dose at the normal time. **Do not take a double dose to make up for a forgotten dose.**

If you forget to take more than one dose, contact your doctor.

If you stop taking Reminyl
Check with your doctor before you stop taking Reminyl. It is important to continue taking this medicine to treat your condition.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Look out for serious side effects

Stop taking Reminyl and see a doctor or go to your nearest emergency department immediately if you notice any of the following:

Skin reactions, including:
- Severe rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome).
- Red rash covered with small pus-filled bumps that can spread over the body, sometimes with a fever (acute generalised exanthematous pustulosis).
- Rash that may blister, with spots that look like small targets.

These skin reactions are rare in people taking Reminyl (may affect up to 1 in 1,000 people).

Heart problems, including changes in heart beat (such as a slow beat, extra beats) or palpitations (heart beat feels fast or uneven). Heart problems may show as an abnormal tracing on an 'electrocardiogram' (ECG), and can be common in people taking Reminyl (may affect up to 1 in 10 people).

Fits (seizures). These are uncommon in people taking Reminyl (may affect up to 1 in 100 people).

You must stop taking Reminyl and get help immediately if you notice any of the side effects above.

Other side effects

Very common side effects (may affect more than 1 in 10 people):
- Nausea and vomiting. These side effects are more likely to happen in the first few weeks of treatment or when the dose is increased. They tend to disappear gradually as the body gets used to the medicine and generally only last for a few days. If you have these effects, your doctor may recommend that you drink more liquids, and may prescribe a medicine to stop you being sick.

Common side effects (may affect up to 1 in 10 people):
- Decreased appetite; weight loss
- Seeing, feeling, or hearing things that are not there (hallucinations)
- Depression
- Feeling dizzy or fainting
- Muscle tremors or spasms
- Headache
- Feeling very tired, weak or generally unwell

- Feeling very sleepy with low energy
- High blood pressure
- Stomach pain or discomfort
- Diarrhoea
- Indigestion
- Falls
- Wounds.

Uncommon side effects (may affect up to 1 in 100 people):
- Allergic reaction
- Not enough water in the body (dehydration)
- Tingling or numb feeling of the skin (pins and needles)
- Change in sense of taste
- Daytime sleepiness
- Problems controlling movements of the body or limbs (extrapyramidal disorder)
- Blurred vision
- Ringing in the ears that does not go away (tinnitus)
- Low blood pressure
- Flushing
- Feeling the need to vomit (retch)
- Excessive sweating
- Weak muscles
- Increased level of liver enzymes in the blood.

Rare side effects (may affect up to 1 in 1,000 people):
- Inflamed liver (hepatitis).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

5. How to store Reminyl

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Reminyl contains

- The active substance is galantamine. Each prolonged-release capsule contains 8 mg, 16 mg or 24 mg of galantamine (as hydrobromide).
- The other ingredients are:
  Diethyl phthalate, ethylcellulose, hypromellose, macrogol 400, maize starch, sucrose, gelatin, titanium dioxide (E171), iron oxide black (E172), shellac and propylene glycol (E1520).
  The 16 mg and 24 mg capsules also contain iron oxide red (E172).
  The 24 mg capsules also contain iron oxide yellow (E172).

What Reminyl looks like and contents of the pack

Reminyl 8 mg capsules are white and marked 'G8'. Each pack contains blisters of 7 or 28 capsules or bottles of 300 capsules.
Reminyl 16 mg capsules are pink and marked 'G16'. Each pack contains blisters of 7, 28, 56 or 84 capsules or bottles of 300 capsules.
Reminyl 24 mg capsules are caramel-coloured and marked 'G24'. Each pack contains blisters of 7, 28, 56 or 84 capsules or bottles of 300 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

Janssen-Cilag SpA, Via C. Janssen, 04100 Borgo San Michele, Latina, Italy.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Reminyl 8 mg, 16 mg, 24 mg Retardkapseln
Belgium	Reminyl 8 mg, 16 mg, 24 mg harde capsules met verlengde afgifte
Denmark	Reminyl 8 mg, 16 mg, 24 mg depotkapsler, hårde
Finland	Reminyl 8 mg, 16 mg, 24 mg depotkapseli, kova
Greece	Reminyl 8 mg, 16 mg, 24 mg καψάκια παρατεταμένης αποδέσμευσης, σκληρά
Ireland	Reminyl XL 8 mg, 16 mg, 24 mg prolonged release capsules
Italy	Reminyl 8 mg, 16 mg, 24 mg capsule rigide a rilascio prolungato
Luxembourg	Reminyl 8 mg, 16 mg, 24 mg, gélules dures à libération prolongée
Norway	Reminyl 8 mg, 16 mg, 24 mg depotkapsler, hard
Portugal	Reminyl 8 mg, 16 mg, 24 mg cápsulas de libertação prolongada
Spain	Reminyl 8 mg, 16 mg, 24 mg cápsulas duras de liberación prolongada
Sweden	Reminyl 8 mg, 16 mg, 24 mg depotkapslar, hårda
UK (Northern Ireland)	Reminyl XL 8 mg, 16 mg, 24 mg prolonged release capsules

This leaflet was last revised in October 2021

More Information

If you live in the Republic of Ireland, further information, advice and support is available from: The Alzheimer Society of Ireland, Alzheimer House, 43 Northumberland Avenue, Dun Laoghaire, Co.

Dublin. Telephone: (01) 284 6616, Fax: (01) 284 6030, e-mail: info@alzheimer.ie, National Helpline (open Monday to Thursday 10am -4pm): 1 800 341 341 or Western Alzheimer Foundation, Mount Street, Claremorris, Co. Mayo. Telephone: 094 624 80. Fax: 094 62560.

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