

PACKAGE LEAFLET: INFORMATION FOR THE USER

Reminyl 4 mg tablets
Reminyl 8 mg tablets
Reminyl 12 mg tablets
galantamine

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you are a carer and will be giving Reminyl to the person you look after, it is also important that you read this leaflet on their behalf.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Reminyl is and what it is used for
2. Before you take Reminyl
3. How to take Reminyl
4. Possible side effects
5. How to store Reminyl
6. Further information

1. WHAT REMINYL IS AND WHAT IT IS USED FOR

Reminyl is an antidementia medicine used to treat the symptoms of mild to moderately severe dementia of the Alzheimer type, a disease that alters brain function.

The symptoms of Alzheimer's disease include increasing memory loss, confusion and behavioural changes. As a result, it becomes more and more difficult to carry out normal daily activities.

These symptoms are believed to be due to a lack of acetylcholine, a substance responsible for sending messages between brain cells. Reminyl increases the amount of acetylcholine in the brain and so could improve the symptoms of the disease.

2. BEFORE YOU TAKE REMINYL

Do not take Reminyl

- If you are allergic (hypersensitive) to galantamine or to any of the other ingredients listed in section 6 of this leaflet
- If you have severe liver and/or severe kidney disease

Take special care with Reminyl

Reminyl should be used in Alzheimer's disease and not other forms of memory loss or confusion.

Medicines are not always suitable for everyone. Your doctor needs to know before you take Reminyl if you suffer from or have suffered in the past from any of the following conditions:

- liver or kidney problems
- a heart disorder (e.g. angina, heart attack, heart failure, slow or irregular pulse)
- electrolyte disturbances (e.g. decreased/increased blood potassium levels)
- peptic (stomach) ulcer disease
- acute abdominal pain
- a disorder of the nervous system (like epilepsy or Parkinson's disease)
- a respiratory disease or infection that interferes with breathing (like asthma, obstructive pulmonary disease or pneumonia)
- if you recently had an operation on the gut or bladder
- if you have difficulties passing urine

If you need an operation which requires a general anaesthetic, you should inform the doctor that you are taking Reminyl.

Your doctor will then decide whether treatment with Reminyl is suitable for you or if the dose needs to be changed.

Taking other medicines

You should always tell the doctor, nurse or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription.

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 muscular weakness)
- pilocarpine (for dry mouth or dry eyes) if taken by mouth.

Some medicines can affect the way Reminyl works, or Reminyl itself can reduce the effectiveness of other medicines taken at the same time. These include:

- paroxetine or fluoxetine (antidepressants)
- quinidine (used for heart rhythm problems)
- ketoconazole (antifungal)
- erythromycin (antibiotic)

- ritonavir (antiviral - HIV protease inhibitor).

Your doctor may prescribe a smaller dose of Reminyl if you are also taking any of the medicines listed above.

Some medicines can increase the number of side effects caused by Reminyl, these include:

- non-steroidal anti-inflammatory painkillers (e.g. ibuprofen) which can increase the risk of ulcers
- medicines taken for heart disorders or high blood pressure (e.g. digoxin, amiodarone, atropine, beta-blockers, or calcium channel blocking agents). If you take medicines for an irregular heart-beat, your doctor may consider an electrocardiogram (ECG).

If you need an operation which requires a general anaesthetic, you should inform the doctor that you are taking Reminyl.

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

Taking Reminyl with food and drink

Reminyl should be taken with food if possible.

Drink plenty of liquids during your treatment with Reminyl, to keep yourself hydrated. See Section 3 of this leaflet for full details about how to take this medicine.

Pregnancy and breast-feeding

Before taking Reminyl, speak to your doctor for advice if you are pregnant, think you could be pregnant, or you are planning a pregnancy.

You should not breastfeed while you are taking Reminyl.

Driving and using machines

Reminyl may cause dizziness or drowsiness, especially during the first few weeks of treatment. If you experience these symptoms, do not drive or use any tools or machinery.

Important information about some of the ingredients of Reminyl

The orange-brown (12 mg) tablets contain the colouring agent orange-yellow S aluminium lake (E110). In some people this colourant may cause an allergic reaction.,

This product contains lactose. 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

Always take Reminyl exactly as your doctor has told you. You should check with your doctor if you have any questions.

How to take Reminyl tablets

Reminyl tablets should be taken twice daily, in the morning and evening, with water or other liquids, and preferably with food.

Reminyl film-coated tablets are available in three strengths: 4 mg, 8 mg and 12 mg. Reminyl is started at a low dose. Your doctor may then tell you to slowly increase the dose (strength) of Reminyl that you take, to find the most suitable dose for you.

1. The treatment is started at 4 mg (1 white tablet) taken twice daily. After 4 weeks of treatment, the dose is increased.
2. You would then take 8 mg (2 white tablets or 1 pink tablet) twice daily. After another 4 weeks of treatment at the earliest, your doctor may decide to increase the dose again.
3. You would then take 12 mg (3 white tablets or 1 pink and 1 white tablet or 1 orange-brown tablet) twice daily.

Your doctor will explain what dose to start with and when the dose should be increased. If you feel that 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 for you and to discuss how you are feeling. Your doctor will also check your weight regularly while you are taking Reminyl.

Liver or kidney disease

- If you have mild liver disease or mild to moderate kidney disease, the above dosing instructions are followed.
- If you have moderate liver disease, treatment is started with the 4 mg tablet once daily in the morning. After one week of treatment, begin taking the 4 mg tablet twice daily for at least 4 weeks. Do not take more than 8 mg twice daily.
- If you have severe liver and/or kidney disease, do not take Reminyl.

If you take more Reminyl than you should

If you take too much Reminyl, contact a doctor or hospital straight away. Take along any remaining tablets and the packaging with you. Signs or symptoms of overdose may include, among others: severe nausea, vomiting, muscle weakness, slow heart beat, 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, you should contact your doctor.

If you stop taking Reminyl

You should consult your doctor before you stop taking Reminyl. It is important to continue taking this medicine to treat your condition.

Children

Reminyl is not recommended for children.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Reminyl can cause side effects, although not everybody gets them. Some of these effects may be due to the disease itself.

Stop taking your medicine and see a doctor immediately if you experience;

- Heart problems including changes in heart beat (slow or irregular)
- Palpitations (pounding heart beat)
- Conditions like blackout
- An allergic reaction. The signs may include a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

Side effects include:

Very Common: affects more than one user in 10.

- Feeling sick and/or vomiting. If these undesired effects occur, they are mainly experienced early on in the treatment or when the dose is increased. They tend to disappear gradually as the body gets used to the treatment and generally will not last for more than a few days. If you have these effects, your doctor may recommend that you drink more liquids and, if necessary, may prescribe a medicine to stop you being sick.

Common: affects 1 to 10 users in 100.

- Weight loss
- Loss of appetite
- Decreased appetite
- Slow heart beat
- Feeling faint
- Dizziness
- Trembling
- Headache
- Drowsiness
- Abnormally tired
- Stomach pain or discomfort
- Diarrhoea
- Indigestion
- Increased sweating
- Muscle spasms
- Falling

- High blood pressure
- Feeling weak
- General feeling of discomfort
- Seeing, feeling, or hearing things that are not real (hallucinations)
- Feeling sad (depression).

Uncommon: affects 1 to 10 users in 1000

- Increased liver enzymes in the blood (laboratory test result that tells how well your liver is working)
- Possible skipped heart beat
- Disturbance in the mechanism of conducting impulses in the heart
- Sensation of abnormal heart beats (palpitations)
- Tingling, pricking, or numbness of the skin
- Change in the sense of taste
- Excessive sleepiness
- Blurred vision
- Ringing or buzzing in the ears (tinnitus)
- Feeling the need to vomit
- Muscle weakness
- Excessive water loss in the body
- Low Blood Pressure
- Reddening of the face
- Allergic reaction.

Rare side effects: affects 1 to 10 users in 10000.

- Inflammation of the liver (hepatitis).

Tell your doctor or pharmacist if you are worried or think that Reminyl is causing you a problem. If you notice any side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE REMINYL

Keep out of the reach and sight of children.

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

This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Reminyl contains:

The active substance is galantamine.

- Reminyl 4 mg film-coated tablets contain 4 mg galantamine (as hydrobromide)
- Reminyl 8 mg film-coated tablets contain 8 mg galantamine (as hydrobromide)
- Reminyl 12 mg film-coated tablets contain 12 mg galantamine (as hydrobromide)

The other ingredients are:

colloidal anhydrous silica, crospovidone, lactose monohydrate, magnesium stearate and microcrystalline cellulose.

Film coat: hypromellose, propylene glycol, talc and titanium dioxide (E171). There is also yellow ferric oxide (E172) in the 4 mg tablet, red ferric oxide (E172) in the 8 mg and 12 mg tablets, and orange-yellow S aluminium lake (E110) in the 12 mg tablet.

What Reminyl looks like and contents of the pack

Reminyl film-coated tablets are available in three strengths, each of which can be recognized by its colour and lettering:

- 4 mg: off-white, round tablets marked 'G4' on one side and 'JANSSEN' on the other side
- 8 mg: pink, round tablets marked 'G8' on one side and 'JANSSEN' on the other side
- 12 mg: orange-brown, round tablets marked 'G12' on one side and 'JANSSEN' on the other side

The 4 mg, 8 mg and 12 mg tablets come in blister packs of 56 tablets.

Marketing Authorisation Holder

Shire Pharmaceuticals Limited, Hampshire International Business Park, Chineham, Basingstoke, Hampshire, RG24 8EP, UK.

Manufacturer

Janssen-Cilag SpA, Via C. Janssen, 04010 Borgo San Michele, Latina, Italy or
McGregor Cory Ltd., Exel, Site 1 Middleton Close Banbury, Oxfordshire,
OX16 4RS, UK.

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

Austria	Reminyl 4 mg, 8 mg, 12 mg - Filmtabletten
Belgium	Reminyl 4 mg, 8 mg, 12 mg omhulde tabletten
Denmark	Reminyl 4 mg, 8 mg, 12 mg filmovertrukne tabletter
Finland	Reminyl 4 mg, 8 mg, 12 mg kalvopäällysteiset tabletit
France	Reminyl 4 mg, 8 mg, 12 mg comprimé pelliculé
Germany	Reminyl 2x täglich 4 mg, 8 mg, 12 mg Filmtabletten

Greece	Reminyl 4mg, 8 mg, 12 mg επικαλυμμένα με λεπτό υμένιο δισκία
Iceland	Reminyl 4 mg, 8 mg, 12 mg filmúhuðaðar töflur
Ireland	Reminyl 4 mg, 8 mg, 12 mg tablets
Italy	Reminyl 4 mg, 8 mg, 12 mg compresse rivestite con film
Luxembourg	Reminyl 4 mg, 8 mg, 12 mg comprimé pelliculé
Netherlands	Reminyl 4 mg, 8 mg, 12 mg, filmomhulde tabletten
Norway	Reminyl 4 mg, 8 mg, 12 mg filmdrasjerte tabletter
Portugal	Reminyl 4 mg, 8 mg 12 mg comprimidos revestidos
Sweden	Reminyl 4 mg, 8 mg, 12 mg filmdragerade tabletter
UK	Reminyl 4 mg, 8 mg, 12 mg tablets

This leaflet was last revised in April 2012

More Information

If you are a person with Alzheimer's disease or are caring for someone, and you are in England, Wales or Northern Ireland, further information, advice and support is available from the Alzheimer's Helpline 0845 300 0336 Monday - Friday 08.30 - 18.30. The helpline is provided by the Alzheimer's Society, Gordon House, 10 Greencoat Place, London SW1P 1PH. Telephone: 020 7306 0606, Fax: 020 7306 0808, e-mail: info@alzheimers.org.uk.

If you are in Scotland, further information, advice and support is available from the 24 hour Dementia Helpline on 0808 808 3000. The helpline is provided by Alzheimer Scotland - Action on Dementia, 22 Drumsheugh Gardens, Edinburgh EH3 7RN. Telephone (office): 0131 243 1453, Fax: 0131 243 1450, email: alzheimers@alzscot.org.

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.

Reminyl is a registered trademark of Shire Pharmaceutical Development Ltd. in the UK and Ireland.