

REMINYL™ ER (EXTENDED RELEASE GALANTAMINE HYDROBROMIDE)

The purpose of this medication

Reminyl ER is one of a group of drugs called "cholinesterase inhibitors" which are used to treat symptoms in people with mild to moderate Alzheimer's disease.

In the brains of people with Alzheimer's disease there is a progressive degeneration of nerve cells, particularly of the cells that make acetylcholine, a chemical thought to be important for learning and memory. Because of this, people with Alzheimer's disease have lower brain levels of acetylcholine. Reminyl ER works principally by reducing the breakdown of acetylcholine and thus increasing the amount of the chemical in the brain.

It has also been suggested, based on data from animal experiments, that the medication enhances the action of acetylcholine by making the receptors it interacts with in the brain more responsive. In the region of the brain first affected by Alzheimer's disease, dealing with cognition and memory, too little acetylcholine is available at the junctions between nerve cells to get messages across to the next nerve cell. The situation is helped, therefore, not only by preserving the acetylcholine from being destroyed by cholinesterase, but by making the receptors more responsive to the lower amounts of acetylcholine. Whether this effect is also true for humans is unknown.

The potential beneficial effect of Reminyl ER could lessen as the disease progresses and when fewer cells are available to make acetylcholine.

Ongoing research is finding that combining cholinesterase inhibitors (such as Reminyl ER, Aricept or Exelon) together with memantine (a drug used to relieve the symptoms of people with moderate to severe Alzheimer's disease) seems to greatly improve outcomes, sometimes more than predicted from the sum of the effects of either drug alone. However, more and larger drug trials are needed to confirm these promising early results.

How does it help?

Reminyl ER is intended to treat symptoms in people with mild to moderate Alzheimer's disease. In clinical trials, some individuals who took the drug, compared to individuals who took a placebo (a substance which looks like the drug but has no effect), showed some improvement or no decline in cognition (including memory, orientation and language) and global functioning (for example, the performance of daily activities such as bathing, dressing and eating).

The medication may take as long as 12 weeks to begin working, and the type and length of response as well as the time it takes for patients to respond to this medication will vary from person to person.

Will this medication cure Alzheimer's disease?

Reminyl ER is not a cure for Alzheimer's disease as it does not affect the underlying degenerative process of the disease.

Who should take this medication?

The medication is approved for people who have been diagnosed with mild to moderate Alzheimer's disease. The use of Reminyl ER is not advised by Health Canada outside of its approved indication.

How do you obtain this medication?

Reminyl ER can only be obtained with a prescription from a doctor after a diagnosis of Alzheimer's disease has been made.

A reminder: This medication has been prescribed only for you or for the person you are caring for. It must not be given to anybody else or used for any other illness.

Important! Things to know before taking this medication:

The doctor should be informed if the person taking the medication is allergic to Reminyl ER or to any of the inactive ingredients in this product or to a similar type of medication.

Reminyl ER extended release capsules come in 3 strengths:

1. 8 mg (white opaque capsule)
2. 16 mg (pink opaque capsule)
3. 24 mg (caramel opaque capsule)

The doctor should be informed if any other medications are being taken, including prescription, over-the-counter and herbal medicines, as well as natural health products.

The doctor should be told if any of the following conditions exist:

- heart disorders
- liver problems
- kidney problems
- stomach ulcer or a history of ulcer
- acute abdominal pain
- disorders of the nervous system (like epilepsy)
- respiratory diseases that interfere with breathing (like asthma)
- a recent operation on the stomach or bladder or difficulties in passing urine
- an increased risk of developing ulcers, for example, currently using non-steroidal anti-inflammatory drugs (NSAIDs) or high doses of acetylsalicylic acid (ASA/Aspirin)

Tell your doctor if you are taking:

- drugs for diarrhea, Parkinson's disease, or airway spasms
- certain drugs for depression such as paroxetine
- ketoconazole a drug used to treat fungal infections
- drugs for certain heart problems such as digoxin

Tell your doctor if you are pregnant, possibly pregnant or a nursing mother. If any of the above conditions happen after starting the medication, make sure you tell your doctor.

Reminyl ER can affect the ability to drive or operate machinery. Therefore, this matter should be discussed with your doctor.

Anaesthetic: If an operation with a general anaesthetic (medication that puts you to sleep) is needed, inform the doctor.

How do you take this medication?

- The medication is started at a low dose and then slowly increased to the most suitable dose for that person, depending on the response to the treatment.
- Reminyl ER capsules should be taken once a day in the morning, preferably with food.
- Be sure to drink plenty of liquids.
- Take only as prescribed by your doctor. Never change the dose yourself.
- To benefit from the medication, it must be taken every day.
- If you miss taking a dose, do not worry. Wait and take the next dose at the usual time. DO NOT take two doses at once.
- If you miss taking the medication for several days, DO NOT restart treatment without contacting your doctor.
- If you have problems remembering to take medications, it may be necessary to have someone manage this for you.
- This medication should not be taken with other cholinesterase inhibitors.

What are the possible side effects?

Along with its beneficial effect, Reminyl ER may cause some undesirable reactions. The most common side effects are nausea and vomiting. These adverse events should be monitored and the doctor informed, if they occur.

Other possible side effects include: abdominal pain, diarrhea, indigestion, decreased appetite, difficulty swallowing, bleeding in the digestive system, weight loss, low blood potassium, low blood pressure, dehydration (sometimes severe), seizures, agitation, aggression, hallucinations, weakness, fever, malaise, leg cramps, tingling in the hands or feet, ringing in the ears, headache, dizziness, tiredness, sleeplessness, runny nose, urinary tract infection, falling (sometimes resulting in injury), fainting or fluttering of the heart.

Side effects are most likely to occur after an increase in dosage and may go away with continued treatment. If they persist, however, tell your doctor.

Infrequently, trembling, a heart rhythm disorder, heart attack or stroke have occurred. Rarely, a slow heartbeat and thoughts of suicide or suicide attempts have occurred. Should such symptoms occur, contact your doctor immediately, as medical assistance might be necessary.

If any of the following symptoms occur contact your doctor immediately:

- pain or tightness in the chest
- sudden weakness or numbness of the face, arms or legs, especially on one side, slurred speech or vision problems
- thoughts of suicide or hurting yourself

If you / the person you are caring for feel unwell in any other way or have any symptoms that you do not understand, or find distressing, you should contact your doctor immediately. If you experience severe adverse events, stop taking the drug until you can discuss your symptoms with your doctor.

In addition, you should contact your doctor if the person experiences any other side effects not mentioned in this information sheet.

What to do if an overdose is taken:

If more medication has been taken than what is prescribed, contact either your doctor, hospital emergency department, or the nearest poison control centre immediately, even if you do not feel sick.

How do you store this medication?

- Store the medication in a cool dry place (between 15°C - 30°C).
- Store in its original package.
- Keep the medication in a safe place out of reach of children.
- Do not use the medication after the expiry date shown on the package.
- If your doctor decides to stop treatment, return any leftover medication to your pharmacist.

How much does it cost and who pays for this medication?

The medication costs approximately \$5.00 per day. It is covered under provincial drug plans in Canada, provided that individuals meet specific clinical criteria for entitlement. The medication is also covered by most private insurance plans.

Who produces this medication?

Janssen Ortho Inc., 19 Greenbelt Drive, Toronto, Ontario, Canada.

For further information

This information sheet is a brief description and summary of information about this medication. If you have any further questions about Reminyl ER, ask your doctor or pharmacist.

The contents of this document are provided for information purposes only, and do not represent advice, an endorsement or a recommendation, with respect to any product, service or enterprise, and/or the claims and properties thereof, by the Alzheimer Society of Canada.

Alzheimer Society

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