



Galantamine hydrobromide (Reminyl) Drug treatment for Alzheimer's disease

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Introduction

Galantamine hydrobromide (marketed as Reminyl) is one of a group of three drugs for people with Alzheimer's disease called cholinesterase inhibitors. The other two are called donepezil hydrochloride (common brand name Aricept) and rivastigmine (common brand name Exelon). See Information sheets 11 and 14 for information on these drugs.

For the purposes of this information sheet, galantamine hydrobromide will be referred to as Reminyl, since it is the brand most people will be familiar with, although other brands may become available.

Reminyl is the name given to the particular brand of galantamine hydrobromide produced by a company called Shire Pharmaceuticals. It is licensed for the treatment of mild to moderately severe Alzheimer's disease.

The severity of an individual's Alzheimer's disease is often defined by their score out of 30 on a test called the Mini Mental State Examination (MMSE):

mild:	MMSE 21–26
moderate:	MMSE 10–20
severe:	MMSE less than 10.

The MMSE is a very basic screening test and most people will undergo a series of tests, scans and assessments leading up to their dementia diagnosis. The MMSE may also be used as one method of determining the progress of a person's illness, but should be combined with other assessments and observations, including those of spouses, partners, family members and other carers.

Reminyl is not claimed to be a cure for Alzheimer's disease. It treats the symptoms only and there is no evidence that it could halt or reverse the process of brain cell damage that causes Alzheimer's disease.

How does Reminyl work?

Acetylcholine is a neurotransmitter, a brain chemical which carries messages between

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brain cells. When someone has Alzheimer's disease, it seems that, among other changes, his or her brain produces less acetylcholine. Normally there is a repeated cycle in the brain in which acetylcholine is made, transmits messages and is then broken down by a special enzyme (acetylcholinesterase).

Reminyl aims to prevent the last part of this cycle so that the acetylcholine is not broken down. There is then more acetylcholine available in the brain to carry messages between the brain cells.

Reminyl also affects another part of the cycle, which results in an improvement in the effectiveness of acetylcholine in carrying messages between brain cells.

Who might benefit?

Reminyl was designed for people with Alzheimer's disease, and not for people with other kinds of dementia. It is licensed for people who are in the mild to moderately severe stages of Alzheimer's disease.

There is some evidence that it might benefit people with mixed dementia (Alzheimer's disease and vascular dementia).

It is important to realise that Reminyl (or any of the other cholinesterase inhibitors) will not help everyone who tries it. Even in those who do benefit, there can be a lot of variation. For some people, the drug may delay or slow the worsening of some symptoms for anything up to six months or a year; others will see the benefit for much longer.

What effect might Reminyl have?

The effect of the drug will vary for different people. Some will not notice an effect at all. Others may find that their condition improves, or that they stay the same for a period of time when they would have been expected to get gradually less able because of the progression of Alzheimer's disease.

Some studies have found that Reminyl improves cognition (mental functions or processes, such as memory) and function (i.e. the person's ability to carry out normal activities).

Some of the benefits may be quite subtle and not easily measured on clinical assessment scales; nevertheless they can improve quality of life of not only the person with dementia, but also the person's main carer.

Benefits may include maintaining the person's mood, being able to cope and interact with others, and carry out basic activities such as being able to pick up the phone or switch on the television.

How is Reminyl taken?

Reminyl comes in three forms: as 8mg and 12 mg tablets; as Reminyl XL in 8mg, 16mg and 24mg prolonged release capsules; and as an oral solution.

You should read the patient information leaflet that comes with each form of the drug and take the drug as directed by the doctor who prescribed it.

Treatment will normally start with a low dose and the doctor will gradually increase the dose, depending on how you respond to the treatment.

Your doctor will need to see you regularly to check that this medicine is working for you and to discuss how you are feeling. He or she will also check your weight regularly while you are taking Reminyl.

8mg and 12 mg film-coated tablets

Reminyl tablets should be taken twice daily, in the morning and evening, with water or other liquids, and preferably with food. You should drink plenty of liquids if taking Reminyl to keep yourself hydrated.

You will start with 4mg twice a day for four weeks. The 4mg tablets have been

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discontinued, the tablets cannot be halved and the tablet is unsuitable for once daily dosing. When commencing galantamine, the twice daily oral solution or the once daily capsule formulation are suitable alternatives. 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. Lactose intolerant patients must be aware that Reminyl tablets contain lactose, whereas the capsules and oral liquid do not.

Reminyl XL

Reminyl XL is a newer form of the drug and comes in 8mg, 16mg and 24mg prolonged release capsules. Prolonged release means the capsules release the medicine more slowly. The recommended starting dose for Reminyl XL capsules is 8mg/day.

These capsules should be swallowed whole, not chewed or crushed and should be taken in the morning, with water or other liquids, and preferably with food. Drink plenty of liquids to keep yourself hydrated.

Reminyl XL is started with the 8 mg capsule taken once daily. After 4 weeks of treatment, the dose is normally increased to the 16 mg capsule once daily. After another 4 weeks of treatment at the earliest, your doctor may decide to increase the dose again to the 24mg capsule once a day.

Note that Reminyl capsules contain bovine gelatine (that is, derived from cattle). Some people may have religious, cultural or personal reasons for not wishing to consume this type of product.

Reminyl capsules are lactose-free.

Oral solution

Reminyl oral solution comes in 4mg/ml doses. It should be taken twice daily, in the morning and evening, preferably with food. You can take the dose directly into your mouth from the syringe, or mixed with a little water, if preferred.

The treatment starts at 4 mg (1 millilitre of solution) taken twice a day. After 4 weeks, the dose is increased to 8 mg (2 millilitres of solution) twice a day. After another 4 weeks of treatment at the earliest, your doctor may decide to increase the dose again to 12 mg (3 millilitres of solution) twice daily.

Reminyl oral solution is lactose-free.

Missed doses

If you miss a dose, omit the forgotten dose and take the next dose at the usual time. Two doses should not be taken at once.

If you have missed several doses, tell the doctor. It may be necessary to start again with a lower dose to build up tolerance.

Are there any side effects?

Medicines can affect people in different ways causing side effects in some but not others. It is not possible to tell who will have side effects and who will not.

The most likely side effects are nausea (feeling sick) and vomiting. These are more common when someone begins to take Reminyl or when the dose is increased, but often settle down with time. If these or any other symptoms occur, tell the doctor at once.

Some people may get other side effects including diarrhoea, indigestion, stomach pain or discomfort, loss of appetite, weight loss, headache, dizziness, tiredness, drowsiness, confusion, slow heartbeat, feeling faint, falling, muscle spasms, high blood pressure, feeling weak, increased sweating, trembling, hallucinations, or depression.

If you experience any side effects at all (including any not mentioned above) you should report this to your doctor at once. In many cases, the side effects will fade but you may need to try a different drug instead.

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Coping with side effects

Although you should report any side effects to your doctor, there are some things you can do yourself to help you cope with some of the more common ones:

- if you feel or are sick or have indigestion or stomach pain, try eating little and often and sticking to simple foods
- If you have diarrhoea, drink plenty of water to make up for lost fluids
- If you develop headaches, ask your pharmacist to recommend a suitable painkiller. If headache persists though, report it to your doctor
- If you feel drowsy, dizzy or tired, you should not do anything that would normally require you to be fully alert, like driving or operating machinery
- If you find yourself sweating more than usual, take care not to become overheated during exercise or hot weather. You may also have to drink more fluids to compensate.

Interactions with other drugs

It is important to tell the doctor about all the drugs that you are taking because Reminyl may interact with them. This includes prescription and non-prescription drugs, vitamins, herbal remedies or dietary supplements.

Interactions with other conditions

You should also tell the doctor about any medical conditions or allergies you have.

Reminyl should not be used by people who have severe liver or kidney disease. Dosage adjustment may be considered in mild to moderate liver or kidney disease. Also, some people may be allergic to some of the ingredients in Reminyl (such as lactose and E110 in the 12mg tablets) and in Reminyl XL (such as sucrose).

Reminyl works by increasing or maintaining levels of acetylcholine in the brain. Other drugs also increase the activity of

acetylcholine and should not be taken in combination with Reminyl as this may lead to increased side effects.

Some other conditions, such as stomach ulcers, lung diseases, asthma, Parkinson's disease, urinary incontinence or some heart diseases might possibly be affected by taking Reminyl. People with some of these conditions may be prescribed anticholinergic medicines. These work by **decreasing** levels of acetylcholine. If taken in combination with Reminyl this could lead to both medicines being less effective, with each drug cancelling out the effects of the other.

Overdose

If you have taken too much Reminyl, contact a doctor or hospital straight away for advice. Take any remaining tablets and the packaging with you. NHS 24 (telephone 08454 24 24 24) may be able to give you advice over the phone when your GP practice or health centre is closed.

How to get Reminyl

NHS prescriptions are now free in Scotland.

Reminyl will normally be prescribed by a specialist doctor (for example, a psychiatrist) but sometimes by a GP with substantial experience in the diagnosis and treatment of dementia. If you need to see a specialist, your GP will arrange this. The doctor prescribing Reminyl should also talk to your main carer (partner, spouse or family member) about your condition and how you are both coping.

The doctor will use his or her clinical judgement to determine whether or not to prescribe the drug for you. Some people may be unable to take Reminyl because of other conditions or medication they are taking and the risk of harmful side effects.

The doctor may decide to try one of the other cholinesterase inhibitors (Aricept or Exelon) instead. Normally, the cheapest drug will be

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selected but the doctor may choose a more expensive drug if there are good clinical reasons for doing so.

Reviews

You should have regular check-ups while taking any of these drugs, particularly in the early stages when the dosage is being determined. If you have a carer, they should be asked about their observations on how you are doing and any changes or side effects they have noticed.

The arrangements for reviews will vary from place to place. People receiving Reminyl are likely to be reviewed at a specialist outpatient clinic (sometimes called a memory clinic); or reviews might take place in your own home, perhaps involving a community psychiatric nurse (CPN); in some cases reviews will be carried out by your GP who will liaise with the hospital specialist.

In Scotland, anyone with a diagnosis of dementia should be placed on their GP dementia register and receive a review at least annually, regardless of whether they are receiving a drug treatment or not.

Stopping the drug

Anyone who wants to stop taking the drug should ideally speak to their doctor first or as soon as possible after stopping the treatment.

If you have been on Reminyl for some time but have started to deteriorate or you and/or your carer feel there is no noticeable benefit for you, the doctor may decide to withdraw the drug.

Guidance from NICE (the National Institute for Health and Clinical Excellence) says that treatment should be continued "only when it is considered to be having a worthwhile effect on cognitive, global, functional or behavioural symptoms".

The decision to stop drug treatment should not be taken simply on the basis of your score on

the commonly used Mini Mental State Examination (MMSE). The doctor should discuss it with you and any carer or family member involved - their knowledge of your abilities and condition are important.

It is likely that your condition will deteriorate after stopping the drug. Some people report an almost immediate effect while others say it takes several days or weeks for a difference to show.

Future developments

A number of drug companies have developed generic forms of the cholinesterase inhibitor drugs, including galantamine hydrobromide. Reminyl is the name given to a particular brand of galantamine produced by a company called Shire Pharmaceuticals.

As these new generic drugs come onto the market, the NHS may start prescribing them instead of, or as well as, Reminyl. So the name on the packaging may not include the word Reminyl.

Warning

Reminyl is one of the drugs currently recommended as a treatment option for managing mild to moderate Alzheimer's disease. Because of this, people with dementia who their doctors believe may benefit from it should have no difficulty obtaining Reminyl. If you or the person you care for are told they cannot have it, there are likely to be good medical reasons which the doctor should explain to you.

No-one should attempt to obtain supplies of Reminyl (or any generic equivalent) by ordering it over the Internet. There are many overseas online pharmacies or websites offering drugs without prescription.

Overseas suppliers are not subject to the same controls as UK companies and many have websites which advertise the supply of drugs which are only available on prescription in Britain.

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Avoid buying prescription drugs from unregulated suppliers. Not only are you potentially putting your health at risk by taking drugs without a medically supervised prescription, there is also no guarantee that the "drug" is what it claims to be. It could also be contaminated by other substances.



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