



Rivastigmine (*Exelon*)

Drug treatment for Alzheimer's disease

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Introduction

Rivastigmine (marketed as Exelon) 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 galantamine hydrobromide (common brand name Reminyl). See Information sheets 11 and 17 for information on these drugs.

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

Exelon is the name given to the particular brand of rivastigmine produced by a company called Novartis. It is licensed for the treatment of mild to moderately severe Alzheimer's

disease and for the treatment of dementia related to Parkinson'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.

Exelon 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 Exelon work?

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

Exelon 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.

Who might benefit?

Exelon 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. More recently, it has been licensed for the treatment of dementia related to Parkinson's disease.

Exelon may help some people with more severe Alzheimer's disease but it is not currently licensed for this use.

There is some evidence that Exelon may be helpful to some people with a specific type of dementia, called Dementia with Lewy Bodies (DLB). It may help with some of the symptoms of DLB such as apathy, hallucinations or aggression, as well as cognitive decline. However, because this use of Exelon would be "off-label" (that is, for a condition the drug is not licensed for), it should only be prescribed by a doctor experienced in working with people with DLB. Similarly, Exelon should only be prescribed for dementia associated with Parkinson's disease by a doctor experienced in working with this patient group.

It is important to realise that Exelon (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 Exelon 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 Exelon 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 Exelon taken?

Exelon is available in three forms – as capsules, in liquid form for people who have difficulty swallowing pills, and as a patch (like a sticking plaster). 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.

Capsules

Exelon capsules come in dosages of 1.5mg, 3mg, 4.5mg and 6mg.

They should be taken twice a day (usually morning and night), with a meal or soon afterwards. The capsules should be swallowed

whole and not crushed or chewed. If swallowing is a problem, speak to the doctor about using either the liquid form or the patch.

You will normally start with a daily dose of 3mg (two of the 1.5mg capsules). The dosage is then increased in increments of 3mg daily at intervals of at least two weeks. Depending on your tolerance, the maximum daily dose is 12mg (a 6mg capsule twice a day)

Exelon capsules are lactose-free.

Note that Exelon 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.

Oral solution

The liquid form of Exelon is taken in 2mg/ml doses. It is taken twice a day, with food. The bottle comes with a dosing oral syringe – you can take the dose directly into your mouth from the syringe, or mixed with a little water, if preferred. Depending on your tolerance, the maximum daily dose is 12mg (or 6mg twice a day). Exelon oral liquid is lactose-free.

Patch

The Exelon patch is applied once a day (preferably the same time of day) to clean, dry, non-hairy and non-irritated skin on the back, upper arm or chest. The patch should be removed after 24 hours and a new patch placed on a different part of the skin. Do not apply a new patch to that same location of skin twice within 14 days. You start with an initial dose of 4.6mg which can be increased to a 9.5mg patch per day if required for at least four weeks.

The patch provides smooth and continuous delivery of the drug through the skin, reducing the nausea and vomiting which can sometimes occur due to peaks in medication levels when the drug is taken by mouth. Any reduction in side effects is obviously good for the person

taking the drug but, in trials, some carers also reported that the patch made it easier to follow a treatment routine.

Missed doses/patches

If you have missed 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.

If you find you have forgotten to apply a patch, apply one immediately. You may apply the next patch at the usual time the next day. Do not apply two patches to make up for the one that you missed. If you have not applied a patch for several days, do not apply the next one before you have talked to your doctor.

Are there any side effects?

Like all medicines, there may be side effects from taking Exelon. Side effects are more common when someone begins to take Exelon or when the dose is increased, but often settle down with time. It is not possible to tell in advance who will have side effects and who will not.

The most likely side effects are feeling dizzy, loss of appetite, and stomach problems such as feeling sick (nausea) or being sick (vomiting), and diarrhoea.

Less common side effects include anxiety, sweating, headache, heartburn, weight loss, stomach pain, feeling agitated, feeling tired or weak, generally feeling unwell, trembling or feeling confused. People with dementia related to Parkinson's disease may be more likely to suffer side effects and can also experience trembling, uncontrollable movements or difficulty controlling movements.

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.

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 Exelon 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.

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 Exelon. People with some of these conditions may be prescribed anticholinergic medicines. These work by **decreasing** levels of acetylcholine. If taken in combination with Exelon this could lead to both medicines being

less effective, with each drug cancelling out the effects of the other.

Exelon 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 Exelon as this may lead to increased side effects.

Overdose

If you have taken too much Exelon, 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 Exelon

NHS prescriptions are now free in Scotland.

Exelon 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 Exelon 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 Exelon 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 (Reminyl or Aricept) instead. Normally, the cheapest drug will be 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 Exelon 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 Exelon 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. Exelon is the name given to a particular brand of rivastigmine produced by a company called Novartis.

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

Warning

Exelon 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 Exelon. 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 Exelon (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.

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.



Dementia Alzheimer Scotland
Action on Dementia

Helpline **24**
HOUR

Freephone **0808 808 3000**
Email: helpline@alzscot.org

Alzheimer Scotland

22 Drumsheugh Gardens, Edinburgh EH3
7RN

Telephone: 0131 243 1453

Fax: 0131 243 1450

Email: alzheimer@alzscot.org

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