



Donepezil hydrochloride (Aricept)

Drug treatment for Alzheimer's disease

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Introduction

Donepezil hydrochloride (marketed as Aricept) is one of a group of three drugs for people with Alzheimer's disease called cholinesterase inhibitors. The other two are called rivastigmine (common brand name Exelon) and galantamine hydrobromide (common brand name Reminyl). See Information sheets 14 and 17 for information on these drugs.

For the purposes of this information sheet, donepezil hydrochloride will be referred to as Aricept, since it is the brand most people will be familiar with, although other brands may become available when the UK patent expires in February 2012.

Aricept is the name given to the particular brand of donepezil hydrochloride produced by a company called Eisai Ltd. 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.

Aricept 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 Aricept 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).

Aricept 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 from Aricept?

Aricept 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.

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

There is some evidence that Aricept 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 Aricept 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.

It is important to realise that Aricept (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 Aricept 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 Aricept improves cognition (mental functions or processes, such as memory) and function (i.e. the person's ability to carry out normal activities).

Many studies have found that Aricept reduces psychotic symptoms (e.g. hallucinations) and some behavioural problems in people with mild to moderate Alzheimer's disease.

Other studies have shown benefits for people with severe Alzheimer's disease and for people with vascular dementia with a mild to moderate cognitive impairment.

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 Aricept taken?

Aricept is available in two forms – as normal tablets and as a tablet which dissolves on the tongue, called Aricept Evess. Both are available in 5mg and 10 mg doses.

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.

Unless you have been told otherwise, take your dose of Aricept, with water, just before bedtime. It can be taken with or without food.

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If you have been prescribed Aricept Evess, you should place the tablet on your tongue and allow it to disintegrate before you swallow it. You may find it helps to swallow it with a drink of water.

Treatment will normally start with a 5mg dose and the doctor will gradually increase the dose, depending on how you respond to the treatment. After about a month, the doctor will check to see if you are tolerating the drug well with no side effects. If there are no side effects but the 5 mg dose doesn't seem to be having any effect on your symptoms, the doctor may recommend taking the larger 10 mg dose. The larger dose may work better. The maximum recommended daily dose is 10 mg.

It may take several weeks before Aricept appears to take effect.

Whichever type of Aricept is taken, it should not be crushed before consuming.

Some patients may be allergic to the lactose content of Aricept tablets. As an alternative, Aricept Evess may be considered, as this does not contain lactose.

Missed doses

If you forget to take a dose, don't worry, just take your dose the next day at the usual time. Do not take more than one dose a day to make up for a missed dose.

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?

Like all medicines, there may be side effects from taking Aricept. Side effects are more common when someone begins to take Aricept or when the dose is increased, but often settle down with time. Side effects are less likely for people who start on the lower (5 mg) dose for at least a month.

It is not possible to tell in advance who will have side effects and who will not.

The most likely side effects are diarrhoea, feeling or being sick, and headaches.

Less common side effects include muscle cramp, tiredness, difficulty in sleeping (insomnia), the common cold, loss of appetite, hallucinations (seeing or hearing things that are not really there), agitation, aggressive behaviour, fainting, dizziness, stomach feeling uncomfortable, rash, itching, passing urine uncontrollably, pain, accidents (patients may be more prone to falls and accidental injury).

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 loss of appetite, 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 tired, dizzy, faint, or have falls, try to get up or move more slowly. If you begin to feel faint, sit or lie down until the feeling passes. You should not drive or operate machinery if affected in this way.

Interactions with other drugs

It is important to tell the doctor about all the drugs that you are taking because Aricept 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 conditions, such as stomach ulcers or lung diseases such as asthma, Parkinson's disease, urinary incontinence or some heart diseases might possibly be affected by taking Aricept. People with some of these conditions may be prescribed anticholinergic medicines. These work by **decreasing** levels of acetylcholine. If taken in combination with Aricept this could lead to both medicines being less effective, with each drug cancelling out the effects of the other.

Also, Aricept contains lactose. If you have been told that you have intolerance to some sugars, you should contact your doctor before taking Aricept.

Aricept 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 Aricept as this may lead to increased side effects.

Overdose

If you have taken too much Aricept, 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 Aricept

NHS prescriptions are now free in Scotland.

Aricept 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

Aricept 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 Aricept for you. Some people may be unable to take Aricept 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 (Exelon or Reminyl) 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 Aricept 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.

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If you have been on Aricept 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 donepezil hydrochloride. Aricept is the name given to a particular brand of donepezil hydrochloride produced by a company called Eisai Ltd.

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

Warning

Aricept 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 Aricept. 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 Aricept (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.

Alzheimer Scotland

22 Drumsheugh Gardens, Edinburgh EH3 7RN

Telephone: 0131 243 1453

Fax: 0131 243 1450

Email: alzheimerscot.org

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Find us on the internet at
www.alzscot.org



Dementia Alzheimer Scotland
Action on Dementia

Helpline **24**
HOUR

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