

PACKAGE LEAFLET; INFORMATION FOR THE USER

Aricept® 5mg Film-coated Tablets Aricept® 10mg Film-coated Tablets

(Donepezil Hydrochloride)

You and your caregiver should read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- 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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

IN THIS LEAFLET:

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1. WHAT ARICEPT IS AND WHAT IT IS USED FOR

ARICEPT (donepezil hydrochloride) belongs to a group of medicines called acetylcholinesterase inhibitors.

Donepezil increases the levels of a substance (acetylcholine) in the brain involved in memory function by slowing down the break down of acetylcholine.

It is used to treat the symptoms of dementia in people diagnosed as having mild and moderately severe Alzheimer's disease. The symptoms include increasing memory loss, confusion and behavioural changes. As a result, sufferers of Alzheimer's disease find it more and more difficult to carry out their normal daily activities.

ARICEPT is for use only in adult patients only.

2. BEFORE YOU TAKE ARICEPT

Do NOT take ARICEPT

- If you are allergic (hypersensitive) to donepezil hydrochloride, or to piperidine derivatives, or to any of the other ingredients of ARICEPT listed in section 6

Take special care with ARICEPT

Tell your doctor or pharmacist before starting to take ARICEPT if you have or have had:

- stomach or duodenal ulcers
- seizures (fits) or convulsions
- a heart condition (irregular or very slow heart beat)
- asthma or other long term lung disease
- liver problems or hepatitis
- difficulty passing urine or mild kidney disease

Also tell your doctor if you are pregnant or think you might be pregnant.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicine. This includes medicines that your doctor has not prescribed for you but which you have bought yourself from a chemist/pharmacist. It also applies to medicines you may take sometime in the future if you continue to take ARICEPT. This is because these medicines may weaken or strengthen the effects of ARICEPT.

Especially tell your doctor if you are taking any of the following types of medicines:

- other Alzheimer's disease medicines, e.g. galantamine
- pain killers or treatment for arthritis e.g. aspirin, non-steroidal anti-inflammatory (NSAID) drugs such as ibuprofen, or diclofenac sodium
- anticholinergics medicines, e.g. tolterodine
- antibiotics e.g. erythromycin, rifampicin
- anti-fungal medicine e.g. ketoconazole
- anti-depressants e.g. fluoxetine
- anticonvulsants e.g. phenytoin, carbamazepine
- medication for a heart condition e.g. quinidine, beta-blockers (propranolol and atenolol)
- muscle relaxants e.g. diazepam, succinylcholine
- general anaesthetic
- medicines obtained without a prescription e.g. herbal remedies

If you are going to have an operation that requires you to have a general anaesthetic, you should tell your doctor and the anaesthetist that you are taking ARICEPT. This is because your medicine may affect the amount of anaesthetic needed.

ARICEPT can be used in patients with kidney disease or mild to moderate liver disease. Tell your doctor first if you have kidney or liver disease. Patients with severe liver disease should not take ARICEPT.

Tell your doctor or pharmacist the name of your caregiver. Your caregiver will help you to take your medicine as it is prescribed.

Taking ARICEPT with food and drink

Food will not influence the effect of ARICEPT.

ARICEPT should not be taken with alcohol because alcohol may change its effect.

Pregnancy and breast-feeding

ARICEPT must not be used while breastfeeding.

If you are pregnant, or think you might be pregnant, ask your doctor for advice before taking any medicine.

Driving and using machines

Alzheimer's disease may impair your ability to drive or operate machinery and you must not perform these activities unless your doctor tells you that it is safe to do so.

Also, your medicine can cause tiredness, dizziness and muscle cramp. If you experience any of these effects you must not drive or operate machinery.

Important information about some of the ingredients of ARICEPT

This medicine contains lactose. If you have been told by your doctor that you have intolerance to some sugars, you should contact your doctor before taking ARICEPT.

3. HOW TO TAKE ARICEPT

How much ARICEPT should you take?

Usually, you will start by taking 5 mg (one white tablet) every night. After one month, your doctor may tell you to take 10 mg (one yellow tablet) every night.

Swallow your ARICEPT tablet with a drink of water before you go to bed at night.

The tablet strength you will take may change depending on the length of time you have been taking the medicine and on what your doctor recommends. The maximum recommended dose is 10 mg each night.

Always follow your doctor's, or pharmacist's advice about how and when to take your medicine.

Do not alter the dose yourself without your doctor's advice.

More information can be found on the back of this leaflet

For how long should you take ARICEPT?

Your doctor or pharmacist will advise you on how long you should continue to take your tablets. You will need to see your doctor from time to time to review your treatment and assess your symptoms.

If you stop taking ARICEPT

Do not stop taking the tablets unless told to do so by your doctor. If you stop taking ARICEPT, the benefits of your treatment will gradually fade away.

If you take more ARICEPT than you should

DO NOT take more than one tablet each day. Call your doctor immediately if you take more than you should. If you cannot contact your doctor contact the local hospital Accident and Emergency department at once. Always take the tablets and the carton with you to the hospital so that the doctor knows what has been taken. Symptoms of overdosing include feeling and being sick, drooling, sweating, slow heart rate, low blood pressure (light-headedness or dizziness when standing), breathing problems, losing consciousness and seizures (fits) or convulsions.

If you forget to take ARICEPT

If you forget to take a tablet, just take one tablet the following day at the usual time. Do not take a double dose to make up for a forgotten tablet. If you forget to take your medicine for more than one week, call your doctor before taking any more medicine.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ARICEPT can cause side effects, although not everybody gets them. The following side effects have been reported by people taking ARICEPT.

Tell your doctor if you have any of these effects while you are taking ARICEPT.

Serious side effects:

You must tell your doctor immediately if you notice these serious side effects mentioned. You may need urgent medical treatment.

- Liver damage e.g. hepatitis. The symptoms of hepatitis are feeling or being sick, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine (affects 1 to 10 users in 10,000)
- Stomach or duodenal ulcers. The symptoms of ulcers are stomach pain and discomfort (indigestion) felt between the navel and the breast bone (affects 1 to 10 users in 1,000)
- Bleeding in the stomach or intestines. This may cause you to pass black tar like stools or visible blood from the rectum (affects 1 to 10 users in 1,000)
- Seizures (fits) or convulsions (affects 1 to 10 users in 1,000)
- fever with muscle stiffness, sweating or a lowered level of consciousness (a disorder known as "Neuroleptic malignant Syndrome") (affects less than 1 user in 10,000)

Very common side effects (affects more than 1 user in 10):

- diarrhoea
- feeling or being sick
- headaches

Common side effects (affects 1 to 10 users in 100):

- muscle cramp
- tiredness
- difficulty in sleeping (insomnia)
- the common cold
- loss of appetite
- hallucinations (seeing or hearing things that are not really there)
- unusual dreams including nightmares
- 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)

Uncommon side effects (affects 1 to 10 users in 1,000):

- slow heart beat

Rare side effects (affects 1 to 10 users in 10,000):

- stiffness, shaking or uncontrollable movement especially of the face and tongue but also of the limbs

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ARICEPT

DO NOT use ARICEPT tablets after the expiry date that is printed on the label. The expiry date refers to the last day of that month.

Do not store this medicine above 30°C. Keep out of the reach and sight of children. If your doctor tells you to stop taking your medicine, you should return any you have not used to your pharmacist.

Medicines should 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 do ARICEPT Tablets contain?

- The active substance is donepezil hydrochloride. The 5mg tablets contain 5mg of donepezil hydrochloride and the 10mg tablet contains 10mg of donepezil hydrochloride.
- The other ingredients are:
Lactose monohydrate
Maize starch
Microcrystalline cellulose
Hyprolose
Magnesium Stearate
Film Coating:
Talc
Macrogol
Hypromellose
Titanium dioxide (E171),
Yellow iron oxide (E172) (10mg tablets only).

What do ARICEPT tablets look like?

Aricept 5mg Tablets are white, round, biconvex tablets with 'ARICEPT' on one side and '5' on the other side.

Aricept 10mg Tablets are yellow, round, biconvex tablets with 'ARICEPT' on one side and '10' on the other side.

Pack size: Aricept Tablets are available in blister packs of 28 tablets.

Product procured from within the EU and repackaged by the Parallel Product Authorisation Holder:

PCO Manufacturing Limited, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

MANUFACTURER

Aricept 5mg Tablets are manufactured by PFIZER PGM, Zone Industrielle 29, route des industries, 37530 Pocé sur Cisse, France **or** Pfizer Limited, Sandwich, Kent, UK or Eisai Manufacturing Ltd., Mosquito Way, Hatfield, Herts, AI 10 9SN, UK.

Aricept 10mg Tablets are manufactured by PFIZER PGM, Zone Industrielle 29, route des industries, 37530 Pocé sur Cisse, France.

PARALLEL PRODUCT AUTHORISATION NUMBERS:

PPA 465/108/1-2

Aricept is a registered trademark of Eisai Co., Ltd

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As the days of the week may not be listed on the blister foil in English, please use the following table should you require a translation:

English	Spanish	French	Greek
Mon (Monday)	Lu (Lunes)	Lun (Lundi)	Δ (Δευτέρα)
Tue (Tuesday)	Ma (Martes)	Mar (Mardi)	Τρ (Τρίτη)
Wed (Wednesday)	Mie (Miércoles)	Mer (Mercredi)	Τε (Τετάρτη)
Thu (Thursday)	Ju (Jueves)	Jeu (Jeudi)	Πέ (Πέμπτη)
Fri (Friday)	Vie (Viernes)	Ven (Vendredi)	Πα (Παρασκευή)
Sat (Saturday)	Sa (Sábado)	Sam (Samedi)	Σ (Σάββατο)
Sun (Sunday)	Do (Domingo)	Dim (Dimanche)	Κ (Η Κυριακή)