

PACKAGE LEAFLET

Package leaflet: Information for the user

Aripil Orotab 5 mg Orodispersible Tablet Aripil Orotab 10 mg Orodispersible Tablet (donepezil hydrochloride)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Aripil Orotab is and what it is used for
2. What you need to know before you take Aripil Orotab
3. How to take Aripil Orotab
4. Possible side effects
5. How to store Aripil Orotab
6. Contents of the pack and other information

1. What Aripil Orotab is and what it is used for

Aripil Orotab contains the active substance donepezil hydrochloride.

It is used for the treatment of dementia. Aripil Orotab (donepezil hydrochloride) belongs to a group of medicines called acetylcholinesterase inhibitors. It is used to treat the symptoms of mild to moderately severe dementia of the Alzheimer type. Dementia of the Alzheimer type is a disease that alters the way the brain works and is common in the elderly. Symptoms include increase in memory loss, increasing confusion and changes in the way you behave, making it more difficult to carry out normal daily activities. It is for use only in adult patients.

2. What you need to know before you take Aripil Orotab

Do not take Aripil Orotab:

- if you are allergic to donepezil hydrochloride, to piperidine derivatives or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before taking Aripil Orotab if you suffer or have ever suffered from any of the following conditions:

- a disorder of the heart (especially if you have an irregular heart beat, sick sinus syndrome, or other conditions that affect the rhythm of the heart). Donepezil may slow down your heart rate
- stomach or duodenal ulcers, or if you are taking non steroidal anti-inflammatory drugs (NSAIDS) (for treatment of pain or arthritis)
- difficulty in passing urine
- fits or seizures: Aripil Orotab may have the potential to cause fits or seizures. Your doctor will monitor your symptoms
- asthma or other lung disease
- liver disease.

Please inform your doctor if you need to have an operation, as the dose of the medication used in anaesthesia may need to be adjusted.

Children and adolescents

Children and adolescents under the age of 18 years of age should not take this medicine.

Other medicines and Aripil Orotab

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, in particular if you are taking any of the following:

- antidepressants (e.g. fluoxetine)
- quinidine (for heart rhythm disorders)
- erythromycin (an antibiotic)
- rifampicin (for treatment of tuberculosis)
- ketoconazole or itraconazole (antifungal)
- carbamazepine or phenytoin (for the control of epilepsy)
- beta blockers (medication for a heart condition)
- non-steroidal anti-inflammatory drugs (for treatment of pain or arthritis).

Aripil Orotab should not be taken with other medicines that act in the same way i.e. increasing the amount of acetylcholine in the brain by blocking its breakdown by the enzyme acetylcholinesterase (e.g. galantamine). Medicines that reduce the amount of acetylcholine may work less well if taken together with Aripil Orotab. If you are unsure please speak to your doctor.

Tell your doctor if you need to have an operation as Aripil Orotab may increase the effect of muscle relaxants used in anaesthesia.

Taking Aripil Orotab with food, drink and alcohol

Take special care if drinking alcohol whilst taking Aripil Orotab as alcohol can reduce the effect of Donepezil.

Pregnancy and breast-feeding

If you are pregnant or trying to become pregnant, do not take Aripil Orotab before speaking to your doctor. Aripil Orotab should not be used in pregnancy unless clearly necessary. Women taking Aripil Orotab should not breast feed.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Do not drive or operate machinery if you feel dizzy, sleepy or get muscle cramps while taking Aripil Orotab. Alzheimer's disease may also impair your ability to drive or operate machinery. You must not perform these activities unless your doctor tells you that it is safe to do so.

3. How to take Aripil Orotab

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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

Adults

The recommended starting dose is 5 mg of donepezil hydrochloride taken once a day for at least one month. Your doctor may increase this to 10 mg of donepezil hydrochloride taken once a day. The maximum recommended daily dose is 10 mg. If you experience an increase in side effects while taking 10 mg each day, tell your doctor or pharmacist.

Use in patients with liver and kidney disease

For adults with mild to moderate liver disease, your doctor may need to adjust your dose. No dosage adjustment is required if you have kidney problems.

Use in children or adolescents

Aripil Orotab is only recommended for adults.

Method of administration:

The tablet should be placed on your tongue and allowed to disintegrate before swallowing, with or without water, according to your preference.

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

If you take more Aripil Orotab than you should

Do not take more than one tablet each day. Contact your doctor or nearest hospital casualty department immediately. Take the container and any remaining tablets with you.

If you take more Aripil Orotab than you should, you might have symptoms such as severe nausea, vomiting, salivation, sweating, slow heartbeat (bradycardia), low blood pressure (hypotension), breathing difficulties (respiratory depression), muscle weakness (collapse) and involuntary contractions of the muscles (convulsions). You could also suffer from an increased muscle weakness which may be a life threatening condition if respiratory muscles are involved.

If you forget to take Aripil Orotab

If you forgot 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, contact your doctor before taking any more medicine.

If you stop taking Aripil Orotab

When treatment is stopped the beneficial effects of Aripil Orotab will decrease gradually.

Do not stop taking your tablets without first discussing with your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

- liver problems including hepatitis (inflammation of the liver characterised by dark urine, pale stools, jaundice, feeling sick and fever); this effect is rare (may affect up to 1 in 1,000 people)
- bleeding and stomach or bowel ulcers; this effect is uncommon (may affect up to 1 in 100 people)
- fits; this effect is uncommon (may affect up to 1 in 100 people)
- fever with muscle stiffness, sweating or a lowered level of consciousness (a disorder called "Neuroleptic Malignant Syndrome"); this effect is very rare (may affect up to 1 in 10,000 people).

Other side effects include:

Very common (may affect more than 1 in 10 people):

- diarrhoea
- feeling sick
- headache.

Common (may affect up to 1 in 10 people):

- being sick
- muscle cramps
- feeling tired
- insomnia (difficulty sleeping)
- common cold
- anorexia (loss of appetite)
- hallucinations (seeing or hearing things that are not real)
- unusual dreams including nightmares
- agitation
- aggressive behaviour
- fainting
- feeling dizzy
- abdominal pain or discomfort
- skin rash and itching
- urinary incontinence
- pain
- accidents.

Uncommon (may affect up to 1 in 100 people):

- slow heartbeat
- an increase in the levels of a substance called creatine kinase in your blood which is involved in metabolism.

Rare (may affect up to 1 in 1,000 people):

- extrapyramidal symptoms (EPS) which include involuntary movements, tremors and rigidity, body restlessness, muscle contractions and changes in breathing and heart rate
- changes in heart rhythm

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 Aripil Orotab

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Aripil Orotab contains

- The active substance is donepezil hydrochloride.
- Aripil Orotab 5 mg orodispersible tablets: Each tablet contains 5 mg donepezil hydrochloride (equivalent to 4.56 mg donepezil).
- Aripil Orotab 10 mg orodispersible tablets: Each tablet contains 10 mg donepezil hydrochloride (equivalent to 9.12 mg donepezil).

The other ingredients are mannitol, silica colloidal anhydrous, hydroxy propyl cellulose, acesulfame potassium, glycine, sodium starch glycolate (Type A), crospovidone (Type A), microcrystalline cellulose, magnesium stearate

Aripil Orotab 10mg orodispersible tablet also contains yellow iron oxide E172.

What Aripil Orotab looks like and contents of the pack

Your medicine is in the form of an orodispersible tablet

5 mg donepezil tablets are white coloured round flat bevelled edged tablets, debossed with “DL 5” on one side and “M” on the other side.

10 mg donepezil tablets are yellow coloured round flat bevelled edged tablets, debossed with “DL 10” on one side and “M” on the other side

Cold form foil OPA/Alu/PVC-Alu blisters in packages of *7, 10, 14, 28, 30, 50, 56, 60, 84, 98, 100, 120 and 180 orodispersible tablets

*Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

McDermott Laboratories Limited. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Manufacturers:

McDermott Laboratories Limited. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Mylan Hungary Kft., H-2900, Komárom, Mylan utca.1, Hungary.

This medicinal product is authorised in the member states of the EEA under the following names:

SE/H/0925/001-002/DC

Austria	Donepezil Arcana 5 mg & 10 mg - Schmelztabletten
Belgium	Donepezil ODIS Mylan 5 mg & 10 mg
Cyprus	Donepezil/Generics
Czech Republic	Donepezil Mylan 5 mg & 10 mg tablety dispergovatelne v ústech
France	Donepezil Mylan 5 mg & 10 mg, comprimé orodispersible
Greece	Donepezil/Mylan
Ireland	Aripil Orotab 5 mg & 10 mg oro-dispersible tablets
Poland	Donegen ODT
Portugal	Donepezilo Mylan
Romania	Donepezil Mylan 5mg & 10 mg comprimate orodispersabile
Slovenia	Donepezil Mylan 5 mg & 10 mg orodisperzibilne tablete
Slovakia	Donepezil Mylan 5mg & 10 mg orodispergovateľné tablety
Spain	Donepezilo FLAS MYLAN Pharmaceuticals 5 mg & 10 mg Comprímidos bucodispersables EFG
Sweden	Donepezil Mylan
United Kingdom	Donepezil Hydrochloride 5 mg & 10 mg Orodispersible tablets

This leaflet was last revised in 06/2015