

## **Package leaflet: Information for the patient**

### **Aripil Orotab 5 mg Orodispersible Tablets Aripil Orotab 10 mg Orodispersible Tablets (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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **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. Donepezil hydrochloride belongs to a group of medicines called acetylcholinesterase inhibitors. Donepezil hydrochloride increases the levels of a substance (acetylcholine) in the brain involved in memory function by slowing down the breakdown of that substance.

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

It is for use in adult patients only.

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

##### **Do not take Aripil Orotab:**

- if you are allergic to donepezil, to piperidine derivative medicines (your doctor or pharmacist can advise on this) or any of the other ingredients of this medicine (listed in section 6).

##### **Warnings and precautions**

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

- a heart rate or rhythm problem (e.g. an irregular heart beat or other conditions that affect the rate or rhythm of the heart)
- stomach or duodenal (gut) ulcers
- difficulty passing urine

- fits or seizures
- stiffness, shaking or uncontrollable movement especially of the face and tongue but also of the limbs (which may have occurred after taking certain medicines and referred to as ‘extrapyramidal’ or ‘Parkinson’s’ like effects)
- asthma or other long-term lung problems
- liver problems.

### **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, tell your doctor or pharmacist if you are taking any of the following:

- other Alzheimer’s disease medicines, e.g. galantamine
- anticholinergics (medicines which typically cause dry mouth, blurred vision and/or drowsiness) e.g. tolterodine (used for bladder problems)
- antidepressants (e.g. fluoxetine)
- erythromycin (an antibiotic)
- rifampicin (for treatment of tuberculosis)
- antifungal medicines e.g. ketoconazole, itraconazole
- carbamazepine or phenytoin (for the control of epilepsy)
- medication for heart conditions e.g. quinidine, beta blockers (e.g. propranolol and atenolol)
- pain killers or treatment for arthritis e.g. acetylsalicylic acid (‘aspirin’), nonsteroidal anti-inflammatory drugs (NSAID) such as ibuprofen, or diclofenac muscle relaxants e.g. diazepam

If you are going to have an operation, including dental surgery, that requires you to have an anaesthetic, tell your doctor, dentist, hospital staff or the anaesthetist that you are taking this medicine.

### **Aripil Orotab with alcohol**

Take special care if drinking alcohol whilst taking this medicine as alcohol can reduce the effect of donepezil hydrochloride.

### **Pregnancy and breast-feeding**

If you are pregnant, think you may be pregnant or are planning to have a baby, do not take this medicine before speaking to your doctor for advice. Donepezil hydrochloride should not be used in pregnancy unless clearly necessary.

Women taking this medicine should not breast-feed.

## **Driving and using machines**

Do not drive or operate machinery if you feel dizzy, sleepy/tired or get muscle cramps while taking this medicine.

Alzheimer's disease may also 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.

## **3. How to take Aripil Orotab**

Always take this medicine exactly as your doctor or pharmacist 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 taken once a day, normally in the evening before you go to bed, for at least one month.

After one month, your doctor may increase this to 10 mg taken once a day, normally in the evening before you go to bed.

The maximum daily dose is 10 mg.

### **Use in patients with liver and kidney disease**

For adults with mild to moderate liver problems, your doctor may need to adjust your dose.

No dosage adjustment is normally required if you have kidney problems.

### **Use in children or adolescents**

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

### **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. You can take this medicine with or without food.

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 if you take more tablets than you should. Take the container and any remaining tablets with you to the hospital so that the doctor knows what has been taken.

Symptoms of taking more than you should include feeling and being sick, salivation, sweating, slow heartrate, low blood pressure (light-headedness or dizziness when standing), breathing problems, losing consciousness, seizures (fits) or convulsions and muscle weakness.

### **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.

**Tell your doctor or go to your nearest hospital casualty department straight away if you have any of the following serious side effects:**

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

- bleeding in the stomach, guts or bowel, or ulcers of the stomach or duodenum (gut). If you are sick you may notice fresh blood or coffee like grounds in the sick, or you may pass black tarry stools (poo) or fresh blood from the rectum (back passage)
- seizures (fits).

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

- liver problems including hepatitis (inflammation of the liver). You may notice dark urine, pale stools, yellowing of the skin and whites of the eyes (jaundice), feel sick and have a fever
- changes in heart rhythm or a very slow heart rate.

Very rare (may affect up to 1 in 10,000 people):

- fever with muscle stiffness, sweating or a lowered level of consciousness (a disorder called "Neuroleptic Malignant Syndrome").

### **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 in sleeping)
- common cold
- anorexia (loss of appetite)

- hallucinations (seeing or hearing things that are not really there)
- unusual dreams including nightmares
- agitation
- aggressive behaviour
- fainting
- feeling dizzy
- abdominal pain or discomfort
- skin rash and itching
- passing urine uncontrollably
- pain
- accidents (patients may be more prone to falls and accidental injury).

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, which may be seen in blood tests.

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

- 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 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](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto: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.
- This medicine does not require any special storage conditions.
- 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 any 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 (E421), silica colloidal anhydrous, hydroxy propyl cellulose, acesulfame potassium, glycine, sodium starch glycolate, crospovidone, microcrystalline cellulose, magnesium stearate.

Aripil Orotab 10 mg orodispersible tablets also contain 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, marked with “DL 5” on one side and “M” on the other side.

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

Aripil Orotab are supplied in blister packs 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**

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

### **Manufacturer**

McDermott Laboratories Ltd. 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:**

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 dispergovatelné 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 Comprimidos bucodispersables EFG
Sweden	Donepezil Mylan
United Kingdom	Donepezil Hydrochloride 5 mg & 10 mg Orodispersible tablets

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