

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

### **Donecept 5 mg film-coated tablets Donecept 10 mg film-coated 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 Donecept is and what it is used for
2. What you need to know before you take Donecept
3. How to take Donecept
4. Possible side effects
5. How to store Donecept
6. Contents of the pack and further information

#### **1. What Donecept is and what it is used for**

Donecept belongs to a group of medicines called acetylcholinesterase inhibitors. It is used to treat the symptoms of dementia in people diagnosed as having mild to moderately severe Alzheimer's disease. Donecept is for use in adult patients only.

#### **2. What you need to know before you take Donecept**

##### **Do not take Donecept**

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

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

Treatment with Donecept should only be started and supervised by a doctor with experience in diagnosing and treating Alzheimer's dementia.

Talk to your doctor or pharmacist before taking Donecept if you:

- have ever had stomach or duodenal ulcers, or if you are taking non steroidal anti-inflammatory drugs (NSAIDs)
- have ever had a seizure. Donepezil may have the potential to cause fits or seizures. Your doctor will monitor your symptoms.
- have or have had a heart condition (such as irregular or very slow heart beat, heart failure, myocardial infarction)
- have or have had a heart condition called 'prolonged QT interval' or a history of certain abnormal heart rhythms called Torsade de Pointes or if anyone in your family have 'prolonged QT interval'
- have or have had low levels of magnesium or potassium in your blood
- have asthma or other long-term lung disease
- have ever had liver disease
- have difficulty passing urine

- are going to have an operation that requires you to have a general anaesthetic, as the dose of the medication used in anaesthesia may need to be adjusted.

### **Children and adolescents**

Donecept is not recommended for children and adolescents below the age of 18 years.

### **Other medicines and Donecept**

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. In particular, it is important to tell your doctor if you are taking any of the following types of medicines:

- medicines for heart rhythm problems e.g. amiodarone, sotalol
- medicines for depression e.g. citalopram, escitalopram, amitriptyline, fluoxetine
- medicines for psychoses e.g. pimozide, sertindole, ziprasidone
- medicines for bacterial infections e.g. clarithromycin, erythromycin, levofloxacin, moxifloxacin, rifampicin
- anti-fungal medicines e.g. ketoconazole
- other Alzheimer's disease medicines e.g. galantamine
- painkillers or treatment for arthritis e.g. aspirin, non-steroidal-anti-inflammatory drugs (NSAIDs) e.g. ibuprofen or diclofenac sodium
- anticholinergic medicines e.g. tolterodine
- anticonvulsants e.g. phenytoin or carbamazepine
- medication for a heart condition e.g. quinidine, beta-blockers (e.g. propranolol and atenolol)
- muscle relaxants e.g. diazepam, succinylcholine
- general anaesthetic
- medicines obtained without a prescription e.g. herbal remedies.

### **Donecept with alcohol**

You must avoid drinking alcohol while you are being treated with donepezil, because it could reduce the effect of donepezil.

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

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Donecept should not be used by breast-feeding women.

### **Driving and using machines**

Donecept and the disease may impair your ability to drive or operate machinery. The medicine can cause fatigue, dizziness and muscle cramp especially in the beginning of treatment, and if affected you must not drive or operate machinery. You should discuss this with your doctor before performing these activities.

### **Donecept contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## **3. How to take Donecept**

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

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 will recommend.

*Donecept 5 mg film-coated tablets only*

Usually, you will start by taking one film-coated tablet (5 mg donepezil hydrochloride) every night. After one month, your doctor may tell you to take two film-coated tablets (10 mg donepezil hydrochloride) every night. The maximum recommended dose is 10 mg each night.

#### *Donecept 10 mg film-coated tablets only*

Usually, you will start by taking 5 mg donepezil hydrochloride every night. After one month, your doctor may tell you to take one film-coated tablet (10 mg donepezil hydrochloride) every night. The maximum recommended dose is 10 mg each night.

For doses not realisable/practicable with this strength other strengths of this medicinal product are available.

Take Donecept by mouth with a drink of water at night before you go to bed.

No dosage adjustment is required if you have kidney problems.

For adults with mild to moderate liver disease, your doctor may need to adjust your dose. There are no data for patients with severe liver impairment.

#### **Use in children and adolescents**

Donepezil is not recommended for children and adolescents.

You should always follow your doctor's advice about how and when to take your medicine. Do not alter the dose yourself without your doctor's advice. Do not stop taking the tablets unless told to do so by your doctor.

#### **For how long should you take Donecept**

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 Donecept than you should**

Do not take more tablets than the doctor has told you. Contact your doctor or hospital immediately if you take more than you should. Always take the tablets and the carton with you to the hospital so that the doctor knows what has been taken.

Symptoms of overdose may include nausea, vomiting, drooling, sweating, slow heartbeat, difficulty breathing, muscle weakness, fainting and seizures.

#### **If you forget to take Donecept**

Do not take a double dose to make up for a forgotten dose.

If you forget to take a tablet, just take one tablet the following day at the usual time. If you forget to take your medicine for more than one week, call your doctor before taking any more medicine.

#### **If you stop taking Donecept**

When treatment is stopped the beneficial effects of donepezil will decrease gradually. Do not stop taking your tablets, even if you are feeling well, unless your doctor tells you.

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.

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

- stomach or duodenal ulcers. The symptoms of ulcers are stomach pain and discomfort (indigestion) felt between the navel and the breast bone (Uncommon: may affect up to 1 in 100 people)
- bleeding in the stomach or intestines. This may cause you to pass black stools or visible blood from the rectum (Uncommon: may affect up to 1 in 100 people)
- seizures (fits) or convulsions (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”, very rare: may affect up to 1 in 10,000 people).
- Muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell, have a high temperature or have dark urine. They may be caused by an abnormal muscle breakdown which can be life threatening and lead to kidney problems (a condition called rhabdomyolysis).

### **Other side effects**

*Very common: may affect more than 1 in 10 people:*

- diarrhoea
- nausea
- headache

*Common: may affect up to 1 in 10 people:*

- common cold
- loss of appetite
- hallucinations, aggressive behaviour, agitation, which have resolved on dose-reduction or discontinuation of treatment.
- dizziness, sleeplessness, fainting
- vomiting, abdominal disturbance
- itching, rash
- muscle cramp
- urinary incontinence
- fatigue, pain
- accidents (patients may be more prone to falls and accidental injury)
- unusual dreams and nightmares

*Uncommon: may affect up to 1 in 100 people:*

- slow heart beat
- minor increase of the muscle enzyme creatine kinase in blood tests

*Rare: may affect up to 1 in 1,000 people:*

- stiffness or uncontrollable movement especially of the face and tongue but also of the limbs
- cardiac disturbances

*Not known: frequency cannot be estimated from available data*

- Changes in the heart activity which can be seen on an electro-cardiogram (ECG) called ‘prolonged QT interval’
- Fast, irregular heart beat, fainting, which could be symptoms of a life-threatening condition known as Torsade de Pointes

### **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 HPRC Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Donecept**

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 blister/tablet container and the outer carton. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Donecept contains**

- The active substance is donepezil hydrochloride. Each film-coated tablet contains donepezil hydrochloride monohydrate equivalent to 5 mg or 10 mg donepezil hydrochloride.
- The other ingredients are: tablet core: lactose monohydrate, maize starch, cellulose microcrystalline, magnesium stearate, tablet coating: polyvinyl alcohol, macrogol 3350, talc, titanium dioxide E171 and iron oxide yellow E172 (only in 10 mg tablet).

### **What Donecept looks like and contents of the pack**

5 mg film-coated tablet is white, round and biconvex engraved with 'DZ 5' on one side.

10 mg film-coated tablet is pale yellow, round and biconvex engraved with 'DZ 10' on one side.

#### *Pack sizes:*

Blister: 7, 28, 30, 50, 50 x 1, 56, 60, 84, 98, 100 or 120 film-coated tablets

Tablet container: 28, 30, 100 and 250 film-coated tablets

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Accord Healthcare Ireland Ltd,  
Euro House,  
Euro Business Park,  
Little Island,  
Cork T45 K857,  
Ireland

### **Manufacturers**

Actavis Ltd., BLB016 Bulebel Industrial Estate, Zejtun ZTN 3000 Malta

Actavis Group PTC ehf., Reykjavikurvegur 76-78, IS-220 Hafnarfjordur, Iceland

Balkanpharma-Dupnitsa AD, 3 Samakovsko Shosse Str., Dupnitsa, 2600, Bulgaria

### **This medicinal product is authorised under the following names:**

Ireland Donecept 5 mg Tablets

Donecept 10 mg Tablets

United Kingdom Donepezil hydrochloride 5mg film-coated tablets

Donepezil hydrochloride 10mg film-coated tablets

**This leaflet was last revised in November 2021.**