

## Package leaflet: Information for the user

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

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

Donepezil belongs to a group of medicines called acetylcholinesterase inhibitors.

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.

Donepezil is for use only in adult patients.

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

##### **Do not take Donepezil**

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

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

Talk to your doctor or pharmacist before taking Donepezil, if you have or have had:

- stomach or duodenal ulcers
- seizures (fits) or convulsions
- a heart condition (such as irregular or very slow heart beat, heart failure, myocardial infarction)
- 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 has 'prolonged QT interval'
- low levels of magnesium or potassium in your blood
- 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.

### **Children and adolescents**

Donepezil Accord is not recommended for use in children and adolescents (younger than 18 years of age).

### **Other medicines and Donepezil**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 psychosis 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
- pain killers or treatment for arthritis e.g. aspirin, non-steroidal anti-inflammatory (NSAIDs) drugs such as ibuprofen, or diclofenac sodium
- anticholinergic medicines, e.g. tolterodine
- 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 Donepezil. This is because your medicine may affect the amount of anaesthetic needed.

Donepezil 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 Donepezil Accord.

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

### **Donepezil with food, drink and alcohol**

Food will not influence the effect of Donepezil.

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

### **Pregnancy, breast-feeding and fertility**

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.

Donepezil should not be used while breastfeeding.

### **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.

### **Donepezil contains lactose**

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 Donepezil.

## **3. How to take Donepezil**

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

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 Donepezil with a drink of water before you go to bed at night.

If you experience abnormal dreams, nightmares or difficulty in sleeping (see section 4) your doctor may advise you to take Donepezil in the morning.

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.

#### **For how long should you take Donepezil?**

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 take more Donepezil than you should**

Contact your doctor or the nearest hospital emergency department immediately if you take more of the medicine than you should. Always take the tablets and the carton with you to the hospital so that the doctor knows what has been taken.

Overdose symptoms may include nausea (feeling sick) and vomiting (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 Donepezil**

If you forget to take your medicine, take the next dose 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.

#### **If you stop taking Donepezil**

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

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.

The following side effects have been reported by people taking Donepezil.

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

#### **Serious side effects:**

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

- stomach or duodenal ulcers. The symptoms of ulcers are stomach pain and discomfort (indigestion) felt between the navel and the breast bone (may affect up to 1 in 100 people)
- bleeding in the stomach or intestines. This may cause you to pass black tar like stools or visible blood from the rectum (may affect up to 1 in 100 people)
- seizures (fits) or convulsions (may affect up to 1 in 100 people)
- 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 (may affect up to 1 in 1,000 people)

- fever with muscle stiffness, sweating or a lowered level of consciousness (a disorder called “Neuroleptic Malignant Syndrome”) (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) (may affect up to 1 in 10,000 people).
- fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as Torsade de Pointes (frequency cannot be estimated from the available data).

### **Other side effects:**

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

- diarrhoea
- feeling sick
- headaches

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

- 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
- vomiting
- rash
- 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 heart beat
- salivary hypersecretion
- minor increase in serum concentration of muscle creatine kinase

#### **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
- disturbance in heart rhythm

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

- Changes in the heart activity which can be seen on an electro-cardiogram (ECG) called ‘prolonged QT interval’
- Libido increased, hypersexuality.
- Pisa syndrome (a condition involving involuntary muscle contraction with abnormal bending of the body and head to one side)

### **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

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 Donepezil**

- 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.
- 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 Donepezil contains**

The active substance is donepezil hydrochloride. Each film-coated tablet contains Donepezil hydrochloride monohydrate equivalent to donepezil hydrochloride 5 mg / 10 mg

The other ingredients are:

**Core:** Lactose monohydrate, maize starch, cellulose microcrystalline, low-substituted hydroxypropyl cellulose, magnesium stearate

**Coating:**

For 5 mg: Hypromellose (E464), titanium dioxide (E171), macrogol 400, talc (E553b)

For 10 mg: Hypromellose (E464), titanium dioxide (E171), macrogol 400, talc (E553b), iron oxide yellow (E172)

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

Donepezil is presented as 5 mg, and 10 mg tablets. The tablets are described below.

5 mg: White to off-white, round, approximately 7.14 mm in diameter, bevelled edge, biconvex, film coated tablets with inscription "5" on one side and plain on other side.

10 mg: Yellow, round, approximately 8.73 mm in diameter, biconvex, film coated tablets with inscription "10" on one side and plain on other side.

Donepezil 5 mg / 10 mg Tablets is available in the following pack sizes:

PVC/Alu Blister in outer carton: 7, 10, 28, 30, 50, 56, 60, 84, 98 and 120 tablets

HDPE Bottle: 100 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

## Manufacturer

Accord Healthcare Polska Sp.z o.o.,  
ul. Lutomska 50,95-200 Pabianice, Poland

**This medicinal product is authorized in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**

Name of the member state	Name of the medicinal product
Bulgaria	Donepezil Hydrochloride Accord 5 mg / 10 mg Филмирани таблетки
Czech Republic	Donepezil Accord 5 mg / 10 mg Potahované tablety
Estonia	Donepezil Accord
Hungary	Donepezil Hydrochloride Accord 5 mg / 10 mg Filmtabletta
Lithuania	Donepezil Accord 5 mg / 10 mg Plėvele dengtos tabletės
Poland	Donatine
Slovak Republic	Donepezil Accord 5 mg / 10 mg filmom obalené tablety
Slovenia	Donepezilijev klorid Accord 5 mg / 10 mg filmsko obložene tablete
Sweden	Donepezil Accord
Austria	Donepezil Accord 5 mg /10 mg Filmtabletten
Cyprus	Donepezil Accord 5 mg / 10 mg επικαλυμμένα με λεπτό υμένιο δισκία
Denmark	Donepezilhydrochlorid Accord 5 mg / 10 mg filmovertrukne tabletter
Finland	Donepezil Accord 5 mg / 10 mg kalvopäällysteinen tabletti/ filmdragerade tabletter
Ireland	Donepezil 5 mg /10 mg Film-coated Tablets
Italy	Donepezil Accord 5 mg / 10 mg Ceompresse Rvestite Ceon Film
Malta	Donepezil 5 mg / 10 mg Film-coated Tablets
Norway	Donepezil Accord 5 mg / 10 mg Filmdrasjerte tabletter
United Kingdom (Northern Ireland)	Donepezil Hydrochloride 5 mg / 10 mg Film-coated Tablets

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