

## Package Leaflet: Information for the User

### Donepezil 5 mg and 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 contains the active substance donepezil hydrochloride. 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 breakdown of acetylcholine.

It is used to treat the symptoms of dementia in people diagnosed as having mild and moderately severe Alzheimer's disease. These 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 in adult patients only.

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

##### **Do NOT take Donepezil:**

- if you are allergic to Donepezil hydrochloride, or to other piperidine derivatives, or 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 have '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 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. 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 some time in the future if you continue to take Donepezil. This is because these medicines may weaken or strengthen the effects of Donepezil.

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 (NSAID) drugs such as ibuprofen, or diclofenac sodium
- anticholinergics 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.

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 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.

Donepezil should not be used while breast-feeding.

#### **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**

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

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

#### **How much ARICEPT should you take**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Initially, the recommended dose is 5 mg (one white tablet) every night before you go to bed. After one month, your doctor may tell you to take 10 mg (one yellow tablet) every night before you go to bed.

If you experience abnormal dreams, nightmares or difficulty in sleeping (see section 4) your doctor may advise you to take Donepezil tablet 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 or pharmacist's advice about how and when to take your medicine. Do not alter the dose yourself without your doctor's advice.

#### **How to take your medicine**

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

#### **Use in Children and adolescents**

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

#### **If you take more Donepezil than you should**

Contact your doctor or nearest hospital emergency department immediately if you take more of the medicine than you should. Take this leaflet and any remaining tablets with you.

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.

**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.

**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.

- liver damage e.g. hepatitis. The symptoms of hepatitis are nausea (feeling sick) or vomiting (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)
- 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)
- 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 and 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 side effects ( may affect more than 1 in 10 people):***

- diarrhoea
- headaches

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

- muscle cramp
- tiredness
- difficulty in sleeping (insomnia)

- the common cold
- hallucinations (seeing or hearing things that are not really there)
- unusual dreams including nightmares
- agitation
- aggressive behaviour
- fainting
- dizziness
- stomach feeling uncomfortable
- rash
- passing urine uncontrollably
- pain
- accidents (patients may be more prone to falls and accidental injury)

***Uncommon side effects(may affect up to 1 in 100 people)***

- slow heart beat
- salivary hypersecretion

***Rare side effects (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

***Not known (frequency cannot be estimated from the available data)***

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

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist . This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 store above 30°C.

DO NOT use this medicine after the expiry date which is stated on the blister and carton 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 dispose of 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. The 5 mg tablet contains 5 mg of Donepezil hydrochloride and the 10 mg tablet contains 10 mg of Donepezil hydrochloride
- The other ingredients are lactose monohydrate, cellulose microcrystalline, magnesium stearate, croscarmellose sodium, talc, macrogol, polyvinyl alcohol, titanium dioxide (E171)
- Additionally, the 10 mg tablet contains synthetic iron oxide yellow (E172).

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

- 5 mg white tablets marked 'D5' on one side and plain on the other.
- 10 mg yellow tablets marked 'D10' on one side and plain on the other.

The tablets are supplied in packs of 7, 14, 28, 30, 50, 56, 60, 84, 98, 112 or 120 tablets. Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

The Marketing Authorisation Holder is:

Ipca Laboratories UK Limited  
Unit 97-98, Silverbriar, Sunderland Enterprise Park East,  
Sunderland, SR52TQ  
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The Manufacturer is:

Niche Generics Ltd  
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151 Baldoyle Industrial Estate  
Dublin 13  
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