

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Donepezil hydrochloride 5mg Film-coated Tablets**  
**Donepezil hydrochloride 10mg 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. 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.

The name of your medicine is **Donepezil hydrochloride 5mg Film-coated Tablets and Donepezil hydrochloride 10mg Film-coated Tablets. But it will be referred to as Donepezil Tablets throughout the leaflet.**

**What is in this leaflet**

1. What Donepezil Tablets are and what they are used for
2. What you need to know before you take Donepezil Tablets
3. How to take Donepezil Tablets
4. Possible side effects
5. How to store Donepezil Tablets
6. Contents of the pack and other information

**1. What Donepezil Tablets are and what they are used for**

Donepezil hydrochloride belongs to a group of medicines called acetyl cholinesterase 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. 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 tablets are for use in adult patients only.

**2. What you need to know before you take Donepezil Tablets****Do NOT take Donepezil Tablets**

- if you are allergic (hypersensitive) to donepezil hydrochloride, or to 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 Tablets if you have or have had:

- stomach or duodenal ulcers
- seizures (fits) or convulsions
- a heart condition (irregular or very slow heart beat)
- 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.

**Other medicines and Donepezil Tablets**

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

Especially tell your doctor if you are taking any of the following types of medicines:

- 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
- anticholinergic medicines, e.g. tolterodine

- antibiotics e.g. erythromycin, rifampicin
- anti-fungal medicine e.g. ketoconazole
- anti-depressants e.g. fluoxetine
- anticonvulsants e.g. phenytoin, carbamazepine
- medicines for heart rhythm problems (e.g. amiodarone, sotalol, and quinidine) beta-blockers (propranolol and atenolol)
- muscle relaxants e.g. diazepam, succinylcholine
- general anaesthetic
- medicines obtained without a prescription e.g. herbal remedies
- depression (e.g. citalopram, escitalopram, amitriptyline), medicines for psychoses (e.g. pimozide, sertindole, ziprasidone), medicines for bacterial infections (such as clarithromycin, erythromycin, levofloxacin, moxifloxacin)

If you are going to have an operation that requires you to have a general anaesthetic, you should tell your doctor and the anaesthetist because your medicine may affect the amount of anaesthetic needed.

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

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

- Food will not influence the effect of Donepezil Tablets.
- Donepezil Tablets should not be taken with alcohol because alcohol may change its effect.

**Pregnancy, breast-feeding and fertility**

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

- Donepezil tablets can cause tiredness, dizziness and muscle cramp. If you experience any of these effects you must not drive or operate machinery.

**Donepezil Tablets contain 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 this medicinal product.

**Information on sodium content**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

**3. How to take Donepezil Tablets**

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

**The recommended dose is:**

- 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 tablets 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 Tablets 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.

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 Tablets than you should**

- DO NOT take more than one tablet each day. Call your doctor

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Front

FLAT DIMENSION = 140 x 430mm

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immediately if you take more than you should. If you cannot contact your doctor, contact the local hospital Accident and Emergency department at once. Always take the tablets and the carton with you to the hospital so that the doctor knows what has been taken.

- Symptoms of overdosing include feeling and 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 Tablets**

- If you forget 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, call your doctor before taking any more medicine.

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

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

#### **4. Possible side effects**

Like all medicines, Donepezil Tablets can cause side effects, although not everybody gets them.

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

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

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

**STOP TAKING** this medicine and tell your doctor immediately if you notice these serious side effects mentioned. You may need urgent medical treatment.

- fever with muscle stiffness, sweating or a lowered level of consciousness (a disorder called “Neuroleptic Malignant Syndrome”).
- 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 (affects 1 to 10 users in 10,000).

- stomach or duodenal ulcers. The symptoms of ulcers are stomach pain and discomfort (indigestion) felt between the navel and the breast bone (affects 1 to 10 users in 1,000).
- bleeding in the stomach or intestines. This may cause you to pass black tar like stools or visible blood from the rectum (affects 1 to 10 users in 1,000).
- seizures (fits) or convulsions (affects 1 to 10 users in 1,000).
- 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).

#### **Very common side effects** (affects more than 1 user in 10):

- diarrhoea
- feeling or being sick
- headaches

#### **Common side effects** (affects 1 to 10 users in 100):

- 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
- rash
- itching
- passing urine uncontrollably
- pain
- accidents (patients may be more prone to falls and accidental injury)

#### **Uncommon side effects** (affects 1 to 10 users in 1,000):

- slow heart beat
- salivary hypersecretion

#### **Rare side effects** (affects 1 to 10 users in 10,000):

- stiffness, shaking or uncontrollable movement especially of the face and tongue but also of the limbs

#### **Frequency Not known** (cannot be estimated from available data)

- Changes in the heart activity which can be seen on an electrocardiogram (ECG) called ‘prolonged QT interval’
- Fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as Torsade de Pointes
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly as below 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 tablets**

- 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 label. The expiry date refers to the last day of that month.
- Store below 25°C in the original packaging.
- 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 Tablets contain**

- 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, Microcrystalline Cellulose, Maize Starch, Hydroxy Propyl Cellulose, Sodium Stearyl Fumarate, Hypromellose, Titanium Dioxide (E171), Purified Talc, Macrogol.
- Additionally, the 10 mg tablet contains ferric oxide yellow (E172).

#### **What Donepezil Tablets look like and contents of the pack**

- **Donepezil 5mg tablets** are white to off white, circular, biconvex, film coated tablet, debossed with “C” on one side and “7” on other side.
- **Donepezil 10mg tablets** are yellow coloured, circular, biconvex, film coated tablets, debossed with “C” on one side and “6” on other side.
- 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**

Name and address: Bristol Laboratories Ltd,  
Unit 3, Canalside, Northbridge Road,  
Berkhamsted, Hertfordshire, HP4 1EG, UK

Telephone: 0044 (0) 1442 200922  
Fax: 0044 (0) 1442 873717  
E-mail: [info@bristol-labs.co.uk](mailto:info@bristol-labs.co.uk)

#### **Manufacturer**

Bristol Laboratories Ltd.  
Unit 5, Traynor Way, Whitehouse Business Park,  
Peterlee, SR8 2RU, United Kingdom.

**Donepezil hydrochloride 5mg film-coated tablets; PL 17907/0404**

**Donepezil hydrochloride 10mg film-coated tablets; PL 17907/0405**

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To request a copy of this leaflet in Braille, large print or audio format, please contact the marketing authorisation holder at the address (or telephone, fax, email) above.

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