

Package leaflet: Information for the user

Donepezil Hydrochloride 5 mg film-coated tablets Donepezil Hydrochloride 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 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

The active ingredient in your medicine is donepezil hydrochloride which 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 break down of acetylcholine.

It is used to treat the symptoms of dementia in people diagnosed as having mild to 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 is 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 to donepezil hydrochloride, or to 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 Tablets if you:

- have ever had stomach or duodenal ulcers
- have ever had a seizure

- have a heart condition (such as irregular or very slow heart beat, heart failure, myocardial infarction)
- have 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
- have asthma or other long term lung disease
- have ever had any severe liver problems. No studies have been done and therefore no information is available on the safe use of Donepezil tablets in patients with severe liver problems.
- have difficulty passing urine or bladder problems
- are pregnant, or think you might be pregnant
- have kidney disease

Children and adolescents

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

Other medicines and Donepezil Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, in particular if you are taking any of the following:

- other Alzheimer’s disease medicines, e.g. galantamine
- non-steroidal anti-inflammatory drugs such as ibuprofen, or diclofenac sodium (for treatment of pain or arthritis)
- anticholinergic medicines, e.g. tolterodine
- antibiotics e.g. erythromycin
- rifampicin (for treatment of tuberculosis)
- anti-fungal medicine e.g. ketoconazole, itraconazole
- anti-depressants e.g. fluoxetine
- anticonvulsants e.g. phenytoin, carbamazepine
- medication for a heart condition e.g. quinidine, beta-blockers (propranolol and atenolol)
- muscle relaxants e.g. diazepam, succinylcholine
- medicines for heart rhythm problems (e.g. amiodarone, sotalol, and quinidine)
- 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 that you are taking Donepezil Tablets. This is because your medicine may affect the amount of anaesthetic needed.

This medicine 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 and drink

Food will not influence the effect of this medicine.

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

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 Tablets should not be used in pregnancy unless clearly necessary.

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.

Also, your medicine can cause fatigue, dizziness and muscle cramps and if affected you must not drive or operate machinery.

Donepezil Tablet contains lactose and sodium

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

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 has told you. Check with your doctor or pharmacist if you are not sure.

Adults: recommended, 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. The maximum recommended dose is 10 mg each 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.

If you experience an increase in side effects while taking 10 mg each day, tell your doctor or pharmacist.

Use in children or adolescents:

Donepezil Tablets are not recommended for children and adolescents under 18 years of age.

Method of administration

Take your Donepezil Tablets by mouth with a drink of water at night before you go to sleep. 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.

Use in patients with liver and kidney disease

If you have mild to moderate liver problems, your dose needs to be gradually and carefully adjusted to your needs by your doctor. If you have severe liver problem, you should take extra care with Donepezil tablets (see section 2, before you take Donepezil tablets). If you have an unexplained liver

disease, your doctor may decide to stop your treatment with Donepezil tablet completely. No dosage adjustment is required if you have kidney problems.

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 Donepezil Tablets than you should

Do not take more than one tablet each day. Contact your doctor or nearest hospital casualty department immediately. Take the container and any remaining tablets with you.

If you take more Donepezil Tablets than you should, you might have symptoms such as severe nausea, vomiting, salivation, sweating, slow heartbeat (bradycardia), low blood pressure (hypotension), breathing difficulties (respiratory depression), muscle weakness (collapse) and involuntary contractions of the muscles (convulsions). You could also suffer from an increased muscle weakness which may be a life threatening condition if respiratory muscles are involved.

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 this medicine, 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.

Serious side effects:

You must 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").
- 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).
- 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 the whites of the eyes, and dark coloured urine
- stomach or duodenal ulcers. The symptoms of ulcers are stomach pain and discomfort (indigestion) felt between the navel and the breast bone
- bleeding in the stomach or intestines. This may cause you to pass black tar like stools or visible blood from the rectum
- seizures (fits) or convulsions

- heart block, a disease in the electrical system of the heart

Other side effects include:

Very common side effects may affect more than 1 in 10 people

- diarrhoea;
- feeling or being sick;
- headaches

Common side effects may affect up to 1 in 10 people

- muscle cramps
- tiredness;
- difficulty in sleeping (insomnia)
- common cold
- loss of appetite
- hallucinations (seeing or hearing things that are not really there)
- agitation;
- aggressive behavior
- fainting;
- dizziness
- stomach feeling uncomfortable
- rash;
- itching
- passing urine uncontrollably
- pain
- accidents (patients may be more prone to falls and accidental injury)
- unusual dreams including nightmares

Uncommon side effects may affect up to 1 in 100 people

- slow heart beat
- an increase in the levels of a substance called creatine kinase in your blood which is involved in metabolism
- salivary hypersecretion

Rare side effects may affect up to 1 in 1,000 people

- Extrapyramidal symptoms (EPS) which include involuntary movements, tremors and rigidity, body restlessness, muscle contractions and changes in breathing and heart rate
- changes 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'
- 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 via the Yellow Card Scheme at: <https://yellowcard.mhra.gov.uk/> 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 after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions. Store in the original package.

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.
 - Donepezil hydrochloride 5 mg film-coated tablets: Each film-coated tablet contains 5 mg donepezil hydrochloride equivalent to 4.56 mg donepezil.
 - Donepezil hydrochloride 10 mg film-coated tablets: Each film-coated tablet contains 10 mg donepezil hydrochloride equivalent to 9.12 mg donepezil.
- The other ingredients are:
 - Tablet core: Lactose monohydrate, maize starch, microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, & magnesium stearate.
 - Film-coating: For 5 mg and 10 mg: hypromellose, polyethylene glycol and titanium dioxide (E171). For 10 mg: iron oxide yellow (E172).

What Donepezil Tablets looks like and contents of the pack:

Donepezil hydrochloride 5 mg film-coated tablets are white coloured, circular, biconvex, film coated tablets with '5' debossed on one side and 'DPZ' debossed on the other side.

Donepezil hydrochloride 10 mg film-coated tablets are yellow coloured, circular, biconvex film coated tablets with '10' debossed on one side and 'DPZ' debossed on the other side.

This medicine is available in blister packs containing 28 tablets.

Marketing Authorisation Holder:

Cipla (EU) Limited, Dixcart House, Addlestone Road, Bourne Business Park, Addlestone, Surrey, KT15 2LE, United Kingdom

Manufacturer:

Cipla (EU) Limited, Dixcart House, Addlestone Road, Bourne Business Park,
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