

Donepezil hydrochloride 5mg and 10mg Tablets

Read all of this leaflet carefully before you start taking this medicine.

- 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 symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- The full name of this medicine is Donepezil hydrochloride 5mg and 10mg Tablets but within the leaflet it will be referred to as Donepezil tablets.

In this leaflet:

- 1 What Donepezil tablets are and what they are used for**
- 2 Before you take**
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1 What Donepezil tablets are and what they are used for

Donepezil tablets belong to a group of medicines called acetylcholinesterase inhibitors. Donepezil tablets are used to treat the symptoms of dementia in people diagnosed as having mild to moderately severe Alzheimer's disease. Donepezil tablets are for use in adult patients only.

2 Before you take

Do not take Donepezil tablets if you are

- **allergic** (hypersensitive) to donepezil hydrochloride, or to piperidine derivatives, or any of the other ingredients of Donepezil tablets
- **pregnant**

Take special care with Donepezil tablets

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

Inform your doctor 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 a **heart condition** (especially if you have an irregular heart beat, sick sinus syndrome, or other conditions that affect the rhythm of the heart), as donepezil may slow down your heart rate.
- 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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is especially important for

- medicines to treat pain and inflammation (NSAID)
- antibiotics such as erythromycin or rifampicin

- anti-fungal medicine, such as ketoconazole or itraconazole
- muscle relaxants, such as succinylcholine
- anti-depressants such as fluoxetine
- anticonvulsants, such as phenytoin or carbamazepine
- medication for a heart condition, such as quinidine, or high blood pressure, such as beta blockers
- other medicines that act the same way as donepezil (such as galantamine or rivastigmine), and some medicines for diarrhoea, Parkinson's disease or asthma.

Taking Donepezil tablets with food and drink

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

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Please contact your doctor as soon as possible if you are pregnant or think you might be pregnant. Donepezil tablets must not be used during pregnancy.

Please contact your doctor if you are breast-feeding.

Donepezil tablets should not be used by breast-feeding women.

Driving and using machines

Donepezil tablets 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.

Important information about some of the ingredients of Donepezil tablets

Donepezil tablets contain 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

Always take Donepezil tablets exactly as your doctor has told you. You should 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.

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

Take Donepezil tablets 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.

If you have severe liver problems, you should take extra care with Donepezil tablets (see section 2 "Before you take"). In cases of unexplained liver dysfunction under treatment with donepezil, withdrawal of Donepezil tablets should be considered.

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 Donepezil tablets

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 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 Donepezil tablets

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 Donepezil tablets

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 product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, Donepezil tablets 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 (which occur in less than 1 of every 1,000 users)
- stomach or duodenal ulcers. The symptoms of ulcers are stomach pain and discomfort (indigestion) felt between the navel and the breast bone (which occur in more than 1 of every 1,000 but less than 1 of every 100 users)
- bleeding in the stomach or intestines. This may cause you to pass black stools or visible blood from the rectum (which occur in more than 1 of every 1,000 but less than 1 of every 100 users)
- seizures (fits) or convulsions (which occur in more than 1 of every 1,000 but less than 1 of every 100 users).

Very common side effects which may occur in more than 1 of every 10 users:

- diarrhoea
- nausea
- headache

Common side effects which may occur in more than 1 of every 100 but less than 1 of every 10 users:

- 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

Uncommon side effects which occur in more than 1 of every 1,000 but less than 1 of every 100 users:

- seizures
- slow heart beat
- gastrointestinal bleeding, stomach and duodenal ulcers
- minor increase of the muscle enzyme creatine kinase in blood tests

Rare side effects which occur in less than 1 of every 1,000 users:

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 How to store

Keep out of the reach and sight of children.

Do not use Donepezil tablets 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What Donepezil tablets contain

- The active substance is donepezil hydrochloride. Each film-coated tablet contains 5mg or 10mg 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 10mg tablet).

What Donepezil tablets look like and contents of the pack

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

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

Pack sizes:
28 film-coated tablets

Marketing Authorisation Holder

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