

PACKAGE LEAFLET: INFORMATION FOR THE USER

DONECEPT

5mg and 10mg Film-coated tablets

HYDROCHLORIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

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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 WHAT YOU NEED TO KNOW BEFORE YOU TAKE DONEPEZIL TABLETS

Do not take Donepezil tablets if you are

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

Warnings and precautions

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

Talk to your doctor or pharmacist before taking Donepezil tablets 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.

Children and adolescents

Donepezil tablets are not recommended for children and adolescents below the age of 18 years.

Other medicines and Donepezil tablets

Please tell your doctor or pharmacist if you are taking, have recently taken or might take 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.
- general anaesthetic.

Donepezil tablets with alcohol

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

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 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.

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 DONEPEZIL TABLETS

Always take this medicine exactly as your doctor has told you. 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.

There are no data for patients with severe liver impairment.

Use in children and adolescents

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 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.

- 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 (Rare: 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 (Uncommon: may affect up to 1 in 100 people)

- bleeding in the stomach or intestines. This may cause you to pass black stools or visible blood from the rectum (Uncommon: may affect up to 1 in 100 people)
- seizures (fits) or convulsions (Uncommon: 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', very rare: 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).

Other side effects

Very common: may affect more than 1 in 10 people

- diarrhoea
- nausea
- headache

Common: may affect up to 1 in 10 people

- 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
- unusual dreams and nightmares

Uncommon: may affect up to 1 in 100 people

- slow heart beat
- minor increase of the muscle enzyme creatine kinase in blood tests

Rare: may affect up to 1 in 1,000 people

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

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: www.mhra.gov.uk/yellowcard

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 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.

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. 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

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