

DONECEPT 5 MG FILM-COATED TABLETS

Actavis

Donepezil hydrochloride

1. What Donecept is and what it is used for

Donecept belongs to a group of medicines called acetylcholinesterase inhibitors. It is used to treat the symptoms of dementia in people diagnosed as having mild to moderately severe Alzheimer's disease. It is for use only in adult patients.

2. Before you take Donecept

a. Do not take Donecept

- if you are allergic (hypersensitive) to donepezil hydrochloride, or to piperidine derivatives, or any of the other ingredients of Donecept
- if you are pregnant

b. Take special care with Donecept

Treatment with Donecept 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.
- are suffering from mild kidney disease

c. Taking other medicines, herbal or dietary supplements

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
- antifungal medicine, such as ketoconazole or itraconazole
- muscle relaxants
- anti-depressants such as fluoxetine
- anticonvulsants, such as phenytoin or carbamazepine
- medication for a heart condition 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.
- anticholinergics medicines, e.g. Tolterodine
- medicines obtained without a prescription e.g. herbal remedies

d. Taking Donecept with food and drink

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

e. Pregnancy and breast-feeding

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

Pregnancy

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

Breastfeeding

Please contact your doctor if you are breast -feeding. Donecept should not be used by breast -feeding women.

f. Driving and using machines

Donecept 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.

g. Important information about some of the ingredients of Donecept

Donecept contains 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 Donecept

Always take Donecept 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 one film-coated tablet (5 mg donepezil hydrochloride) every night. After one month, your doctor may tell you to take two film-coated tablets (10 mg donepezil hydrochloride) every night. The maximum recommended dose is 10 mg each night.

Take Donecept 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 Donecept (see Section 2. "Before you take Donecept"). In cases of unexplained liver dysfunction under treatment with donepezil, withdrawal of Donecept 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 Donecept

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.

a. If you take more Donecept 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.

b. If you forget to take Donecept

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.

c. If you stop taking Donecept

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, Donecept can cause side effects, although not everybody gets them.

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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 7,000 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 Donecept

Keep out of the reach and sight of children.

Store below 30°C.

Do not use Donecept after the expiry date which is stated on the carton and the blister strip.

Do not use Donecept if you notice visible signs of deterioration.

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

a. What Donecept contains

- The active substance is Donepezil hydrochloride. Each film-coated tablet contains 5 mg Donepezil hydrochloride
- The other ingredients are-

Tablet core: Lactose monohydrate, Maize starch, Cellulose microcrystalline and Magnesium stearate

Tablet coating: Polyvinyl alcohol, Macrogol 3350, Talc and Titanium dioxide (E171)

b. What Donecept looks like and contents of the pack

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

Pack size: 28 film-coated tablets

c. Marketing Authorisation Holder and Manufacturer

Manufacturer: Actavis Ltd./ Malta

Packed by: DEEF Pharmaceutical Industries Co./ Al-Gassim/ Al Badaya/ Kingdom of Saudi Arabia

MA Holder: Actavis Group PTC ehf, Reykjavikurvegur 76-78/220 Hafnarfjordur, Iceland
Tel.: (+354)5352300 Fax: (+354)5352301

d. This leaflet was last approved in August 2012.

To report any side effects(s):

National Pharmacovigilance Center (NPC)

- Fax: +966-11-205-7662
- E-mail: npc.drug@sfda.gov.sa
- Website: www.sfda.gov.sa/npc