

PACKAGE LEAFLET: INFORMATION FOR THE USER

Donepezil Hydrochloride 5mg Film-Coated Tablets
Donepezil Hydrochloride 10mg Film-Coated Tablets
(Referred to as Donepezil Tablets in the remainder of the leaflet)



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

Donepezil Tablets contain the active substance donepezil hydrochloride. Donepezil Tablets (donepezil hydrochloride) belong 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 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 to donepezil hydrochloride, 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)
- 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.

Children and adolescents

Donepezil Tablets are not recommended for use in children and adolescents (younger than 18 years of age).

Other medicines and Donepezil Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that your doctor has not prescribed for you but which you have bought yourself from a chemist/pharmacist. It also applies to medicines you may take some time in the future if you continue to take Donepezil Tablets. This is because these medicines may weaken or strengthen the effects of Donepezil Tablets.

In particular it is important to 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
- anticholinergics 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
- medication for a heart condition e.g. quinidine, beta-blockers (propranolol and atenolol)
- muscle relaxants e.g. diazepam, succinylcholine
- general anaesthetic
- medicines obtained without a prescription e.g. herbal remedies

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.

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 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 any medicine.

Donepezil Tablets should not be used while breast-feeding.

Driving and using machinery

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

Donepezil Tablets 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 Donepezil Tablets

How much Donepezil Tablets should you take

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Initially, the recommended dose is 5 mg every night. After one month, your doctor may tell you to take 10 mg every night.

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.

Do not alter the dose yourself without your doctor's advice.

How to take your medicine

Swallow your Donepezil Tablet with a drink of water before you go to bed at night.

Use in children and adolescents

- Donepezil Tablets are not recommended for use in children and adolescents (younger than 18 years of age).

If you take more Donepezil Tablets than you should

Contact your doctor or the nearest hospital emergency department immediately if you take more of the medicine than you should. Take this leaflet and any remaining tablets with you.

Overdose symptoms may 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 your medicine, take the next dose at the usual time.





Do not take a double dose to make up for a forgotten tablet.

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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

For how long should you take Donepezil Tablets?

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.

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:

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 (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 (may affect up to 1 in 100 people)
- bleeding in the stomach or intestines. This may cause you to pass black tar like stools or visible blood from the rectum (may affect up to 1 in 100 people)
- seizures (fits) or convulsions (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") (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) (may affect up to 1 in 10,000 people)
- Delayed or blocked electrical impulse from the sino-atrial node to the atria (sino-atrial block) (may affect up to 1 in 1000 people)
- Delayed or blocked electrical impulse between the atria and ventricles of the heart (atrioventricular block) (may affect up to 1 in 1000 people)

Other side effects

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

- diarrhoea
- feeling sick
- headache

Common side effects (may affect up to 1 in 10 people):

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

- slow heart beat
- salivary hypersecretion

Rare side effects (may affect up to 1 in 1000 people):

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

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 national reporting systems listed below:

United Kingdom:

Yellow Card Scheme

Website:

www.mhra.gov.uk/yellowcard

Ireland:

HPRA Pharmacovigilance,

Earlsfort Terrace, IRL - Dublin 2;

Tel: +353 1 6764971;

Fax: +353 1 6762517;

Website: www.hpra.ie;

e-mail: medsafety@hpra.ie

Malta:

ADR Reporting

Website:

www.medicinesauthority.gov.mt/adrportal

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.

- this medicinal product does not require any special storage conditions.
- Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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 Donepezil 5 mg Tablet contains 5 mg of donepezil hydrochloride.

Each Donepezil 10 mg Tablet contains 10 mg of donepezil hydrochloride.

The other ingredients are: lactose monohydrate, microcrystalline cellulose, maize starch, hydroxypropylcellulose (E463), magnesium stearate, hypromellose, talc (E553b), polyethylene glycol, and titanium dioxide (E171).

Donepezil 10 mg Tablets also contain yellow iron oxide (E172).

What Donepezil Tablets looks like and contents of the pack

Donepezil 5mg Tablets are white to off white, round, biconvex, film-coated tablets debossed with 'W' on one side and '311' on the other side.

Donepezil 10mg Tablets are yellow, round, biconvex, film-coated tablets debossed with 'W' on one side and '312' on the other side.

Both strengths of tablet are available in tablet containers (HDPE) of 28, 30 or 100 tablets. They are also available in blister packs (PVC/PVDC/aluminium) of 7, 14, 28, 30, 50, 56, 60, 84, 98, 112 or 120 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

These medicinal products are authorised in the Member States of the EEA under the following names:

Cyprus

Donepezil Hydrochloride Wockhardt 5 mg Επικαλυμμένα με λεπτό υμένιο δισκία

Donepezil Hydrochloride Wockhardt 10 mg Επικαλυμμένα με λεπτό υμένιο δισκία

Ireland

Donepezil Hydrochloride 5 mg

Film-Coated Tablets

Donepezil Hydrochloride 10 mg

Film-Coated Tablets

Malta

Donepezil Hydrochloride 5 mg

Film-Coated Tablets

Donepezil Hydrochloride 10 mg

Film-Coated Tablets

United Kingdom

Donepezil Hydrochloride 5 mg

Film-Coated Tablets

Donepezil Hydrochloride 10 mg

Film-Coated Tablets

This leaflet was last revised in 07/2017.