

PACKAGE LEAFLET: INFORMATION FOR THE USER
Donepezil hydrochloride 5 mg / 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.



Donepezil hydrochloride film-coated Tablets will be referred to as Donepezil Tablets in this leaflet.

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

Donepezil hydrochloride belongs 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**.

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 similar medicines (known as 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:

Please tell your doctor:

- if you are going to have an **operation** that requires you to have a **general anaesthetic**. Donepezil may exaggerate muscle relaxation during anaesthesia.
- if you have or ever had a **heart problem** (specifically the sick sinus syndrome or a comparable condition). Donepezil may slow down your heart rate.
- if you ever had **stomach or duodenal ulcers** or if you use a certain type of **painkiller** (Non-Steroidal Anti-Inflammatory Drugs – NSAIDs, e.g. diclofenac). Concurrent use may lead to an increased risk of stomach or duodenal ulcers. Your doctor will monitor your symptoms (such as pain of the stomach or the intestine).
- if you have **difficulty passing urine**. Your doctor will monitor your symptoms.
- if you ever had a **seizure**. Donepezil may cause a new seizure. Your doctor will monitor your symptoms.
- if you ever had extrapyramidal symptoms (uncontrolled movements of the body or face). Donepezil may induce or exacerbate extrapyramidal symptoms.
- if you have **asthma or other long term lung disease**. Your symptoms could get worse.
- if you ever had any **liver problems** (as your dose may need to be adjusted).

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.

Children and adolescents

Donepezil Tablets is not recommended for children and adolescents below the age of 18 years.

Other medicines and Donepezil Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Other medicines may be affected by donepezil. They, in turn, may affect how well donepezil works. Donepezil can interact with:

- medicines used to control heart rhythm (**quinidine**), antifungal medicines (**ketoconazole and itraconazole**), specific types of antibiotics (**erythromycin**) and medicines used for the treatment of depression (selective serotonin-reuptake inhibitors, SSRIs, such as **fluoxetine**). These medicines can intensify the effect of donepezil.
- medicines used for the treatment of tuberculosis (**rifampicin**), medicines used to treat epilepsy (**phenytoin and carbamazepine**). These medicines can reduce the effect of Donepezil Tablets.
- medicines used as short-term muscle relaxation in anaesthesia and intensive care (**succinylcholine**) and certain blood pressure lowering medicines (**beta blockers**). The effect of both medicines is increased.
- other medicines that act the same way as donepezil (such as galantamine or rivastigmine), and some medicines for diarrhoea, Parkinson's disease or asthma (agonists or antagonists of the cholinergic system).
- general anaesthetics.
- painkillers or treatment for arthritis such as acetylsalicylic acid, non-steroidal anti-inflammatory (NSAID) medicines such as ibuprofen, or diclofenac.

Donepezil Tablets with food and drink and alcohol

Do not drink any alcohol during treatment with donepezil because alcohol may reduce its effectiveness.

Pregnancy, breast-feeding and fertility

Donepezil Tablets should not be used while breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

Donepezil has a minor or moderate influence on the ability to drive and use machines.

Alzheimer's disease may impair your ability to drive or use machinery and you must not carry out these activities, unless your doctor tells you that it is safe to do so.

Also, Donepezil Tablets can cause **fatigue, dizziness and muscle cramp**, mainly at the start of treatment or after a dose increase. If you are affected, **do 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

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Tell the doctor or pharmacist the name of your caregiver. Your caregiver will help you take your medicine as it is prescribed.

The recommended dose is:

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

For doses not realisable/practicable with this strength other strengths of this medicinal product are available.

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

No dosage adjustment is required if you have **kidney problems**.

If you have **liver problems**, your dose may need to be adjusted to your needs by your doctor (see section 2, What you need to know before you take Donepezil Tablets).

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

This medicine is **not recommended** for use in **children and adolescents (younger than 18 years)**.

Your doctor will tell you 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. Do not stop taking the tablets unless your doctor advises you to.

If you take more Donepezil Tablets than you should

Do not take more tablets than you should. If you take more donepezil than you should, you may experience symptoms such as severe nausea, vomiting, secretion of saliva (salivation), sweating, slow heartbeat (bradycardia), low blood pressure (hypotension), breathing difficulties (respiratory depression), collapse, involuntary contraction of muscles (convulsion) and increased muscle weakness. Call your doctor immediately. If you cannot contact your doctor, contact the local hospital Accident and Emergency department at once. Take the tablets and the carton with you to the hospital, so that the doctor knows what has been taken.

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 tablets for more than one week, call your doctor before taking any more.

If you stop taking Donepezil Tablets

Do not stop treatment without talking to your doctor first, even if you feel better.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. In most cases, these go away without having to stop treatment.

Very common (affects more than 1 user in 10): diarrhoea, nausea (feeling sick) and headaches.

Common (affects 1 to 10 users in 100): common cold, vomiting (being sick) and abdominal disturbances, muscle cramps, fatigue, fainting, dizziness, insomnia (difficulty sleeping), pain, loss of appetite, itching, skin rash, hallucinations, unusual dreams including nightmares, agitation, aggressive behaviour, urinary incontinence, being prone to accidents.

Cases of hallucinations, unusual dreams including nightmares, agitation and aggressive behaviour have been resolved on dose-reduction or withdrawal of Donepezil Tablets.

Uncommon (affects 1 to 10 users in 1,000): seizures, slow heartbeat, stomach and duodenal ulcers and abdominal disturbances including bleeding in the digestive system (this may cause you to pass black tar like stools or visible blood from the rectum), minor increase in serum concentration of a certain muscle enzyme (creatinase).

Rare (affects 1 to 10 users in 10,000): liver disorders (including hepatitis), uncontrolled movements of the body or face (extrapyramidal symptoms), disorders of the electrical conduction system of the heart (sino-atrial block, atrioventricular block).

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

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 bottle/blister and the outer carton after Exp. 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 medicine 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 5mg tablet contains 5 mg of donepezil hydrochloride, equivalent to 4.56 mg of donepezil, and each 10mg tablet contains 10 mg of donepezil hydrochloride, equivalent to 9.12 mg of donepezil.

The other ingredients are:

Tablet core: Lactose monohydrate, maize starch, microcrystalline cellulose, hydroxypropyl cellulose, magnesium stearate. *Film-coating:* hypromellose, macrogol 400, titanium dioxide (E171). A colorant called yellow iron oxide (E172) is also present in the 10mg tablet.

What Donepezil Tablets look like and contents of the pack

Donepezil 5 mg Tablets are white round biconvex film-coated tablets marked 'DNP' on one side and '5' on the other, whereas Donepezil 10 mg Tablets are yellow round biconvex film-coated tablets marked 'DNP' on one side and '10' on the other.

The medicinal product is available in cartons of 7, 28, 30, 50, 56, 60, 84, 98 or 120 film-coated tablets, and in bottles of 28, 30 or 100 film-coated tablets. Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer:

Dr. Reddy's Laboratories (UK) Ltd, 6 Riverview Road, Beverley, HU17 0LD

This medicinal product is authorised in the Member States of the EEA under the following names:

Germany: Donepezil-HCl beta 5 mg & 10 mg Filmtabletten
Spain: Donepezil Aphar 5 mg & 10 mg Comprimidos recubiertos EFG
Italy: Donepezil Dr. Reddy's 5 mg & 10 mg compresse rivestite con film
UK: Donepezil hydrochloride 5 mg & 10 mg film-coated Tablets
Romania: Aldemiz 5 mg & 10mg, comprimate filmate

This leaflet was last revised in July 2012

PL 08553/0313 and 08553/0314