

DONEZIL



Donepezil hydrochloride 5mg & 10mg Tablets

What is in this leaflet

This leaflet answers some common questions about DONEZIL tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking DONEZIL tablets against the benefits they expect it will have for you. If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What DONEZIL is used for and how it works

DONEZIL contains the active ingredient, donepezil hydrochloride. DONEZIL belongs to a group of medicines called acetylcholinesterase inhibitors. They are thought to work by increasing the level of a chemical called acetylcholine in the brain.

DONEZIL tablets are used to treat mild, moderate and severe Alzheimer's disease, also called dementia of the Alzheimer's type. DONEZIL will not cure this disease, but should help your memory and improve your thinking capacity.

Your doctor may however, have prescribed it for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

There is no evidence that DONEZIL is addictive.

DONEZIL is only available with a doctor's prescription.

Before you take DONEZIL

When you must not take it

Do not take DONEZIL if you have an allergy to:

- Any medicine containing donepezil hydrochloride
- Piperidine derivatives
- Any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not give DONEZIL to children. The safety and effectiveness of DONEZIL in children have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

Talk to your doctor or pharmacist if you are not sure whether you should take this medicine.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you have, or have ever had any of the following health problems:

- Heart problems
- Stomach problems, particularly gastric or duodenal ulcer
- Seizure or fits
- Asthma or any other respiratory (lung) problems
- A tendency towards aggressive behaviour.

Tell your doctor if you are pregnant or intend to become pregnant. The safety of DONEZIL in pregnancy is not yet known. Your doctor will discuss the risks and benefits of using DONEZIL if you are pregnant.

Tell your doctor if you are breast-feeding or planning to breast-feed. It is not yet known how much DONEZIL will pass through into breast milk.

Tell your doctor if you plan to go to hospital for surgery that requires a general anaesthetic. Your doctor may ask you to stop taking DONEZIL before you have surgery.

If you have not told your doctor or pharmacist about any of the above, tell them before starting taking DONEZIL.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by DONEZIL, or may affect how well it works. These include:

- Any other medicine used for Alzheimer's disease
- Some medicines used to relieve stomach cramps or spasms, Parkinson's disease or travel sickness
- Some medicines used to treat difficulty in passing urine
- Non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to treat arthritis, pain or inflammation
- Some medicines used to relax muscles e.g. succinylcholine
- Some medicines used to treat high blood pressure or fast heart beat
- Some medicines used to treat irregular heart rhythm e.g. quinidine
- Medicines used in general anaesthesia
- Carbamazepine, phenobarbitone or phenytoin, medicines used to treat epilepsy
- Some medicines used to treat fungal infections e.g. ketoconazole
- Some antibiotics e.g. erythromycin, rifampicin
- Fluoxetine, a medication used for depression
- Dexamethasone, a corticosteroid medicine.

These medicines may be affected by DONEZIL or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

If you are not sure if you are taking any of these medicines, ask your doctor or pharmacist. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking DONEZIL.

How to take DONEZIL

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The usual starting dose for DONEZIL is one 5mg tablet each day. After one month, your doctor will assess your response. Depending on your condition and how you react to the medicine, your doctor may increase your dose to one 10mg tablet each day.

How to take it

Swallow the tablets with a glass of water, do not crush or chew them. DONEZIL tablets can be broken in half if your doctor has prescribed half of a tablet.

DONEZIL can be taken with or without food.

Take the tablet every night just before you go to bed.

How long to take it

It is important to keep taking DONEZIL for as long as your doctor recommends. Do not stop taking your medicine without consulting with your doctor first.

DONEZIL helps to control your condition, but it does not cure it. It may take several weeks for DONEZIL to take effect, so do not be discouraged if you do not see an immediate improvement.

If you forget a dose

If you forget to take a dose, skip the dose you missed, and take your next dose at the normal time the next day, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you forget to take it for more than one week, contact your doctor before taking any more.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking DONEZIL

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking DONEZIL.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking DONEZIL as it may affect other medicines used during surgery. Your doctor may ask you to stop taking DONEZIL before you have surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not give DONEZIL to anyone else. It may not be suitable for them even if they have the same condition as you.

Do not use DONEZIL to treat any other complaints unless your doctor tells you to.

Do not take DONEZIL with alcohol. Taking DONEZIL with alcohol may affect how well it works.

Things to be careful of

Be careful driving or operating machinery until you know how DONEZIL affects you. DONEZIL may cause fatigue, dizziness and muscle cramps especially at the start of treatment or when the dose is increased. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Also, Alzheimer's disease may affect your ability to drive or operate machinery. Ask your doctor whether it is safe for you to continue to drive or operate machinery.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DONEZIL. This medicine helps most people with Alzheimer's disease, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Headache, dizziness
- Fainting
- Difficulty in sleeping
- Tiredness, drowsiness
- Feeling sick, diarrhoea, vomiting,
- Loss of appetite, weight loss
- Muscle cramps, joint pain
- Depression, unusual dreams
- Agitation, aggressive behaviour
- Passing urine more often.

The above list includes the more common side effects associated with DONEZIL. They are usually mild and short-lived

Tell your doctor as soon as possible if you notice any of the following:

- Seeing, feeling or hearing things that are not there
- Trembling and shaking of the hands and fingers, shuffling walk and stiffness of the arms and legs
- Severe upper stomach pain, often with nausea, vomiting and fever.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If you notice any of the following, tell your doctor immediately or go to the Emergency department at your nearest hospital:

- Any breathing problems
- Allergic reactions such as rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing.
- Fainting, especially if you have a slow or irregular heart beat
- Vomiting blood or material that looks like coffee grounds
- Black sticky bowel motions
- Convulsions or fits
- Weakness, shortness of breath, yellowing of the skin, dark brown urine and stomach pain
- Sudden increase in body temperature, extremely high blood pressure and severe convulsions.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by the above lists of side effects. You may not experience any of them.

Tell your doctor if you notice anything else that is making you feel unwell. Other undesirable effects not listed above may also occur in some people.

In case of overdose

You must only take the number of tablets that you have been told.

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any DONEZIL by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

Symptoms of an overdose may include feeling sick in the stomach, vomiting, and increased sweating or saliva production. You may also have a slow heart beat, have trouble breathing, feel faint or dizzy, have fits, feel weak or not be able to control your bowel motions or passing of urine.

Storage conditions

Storage

Keep your DONEZIL in the pack until it is time to take them.

Keep your DONEZIL in a cool dry place where the temperature stays below 25°C.

Do not store DONEZIL or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a half metres above the ground is a good place to store medicines.

Disposal

Do not use the medicine after the expiry date printed on the pack.

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What DONEZIL looks like

DONEZIL 5 mg: White, round, film-coated tablets, embossed with "DL" scoreline "5" on one side and "G" on the reverse.

DONEZIL 10 mg: White, round, film-coated tablets, embossed with "DL" scoreline "10" on one side and "G" on the reverse.

DONEZIL 5mg and 10mg tablets are available in blisters of 28 tablets

Ingredients

DONEZIL film-coated tablets for oral administration are supplied containing 5 mg or 10 mg donepezil hydrochloride equivalent to 4.56 mg or 9.12 mg donepezil free base, respectively.

The tablets also contain: lactose, maize starch, microcrystalline cellulose, hydroxypropyl cellulose and magnesium stearate.

The film-coat contains hypromellose, titanium dioxide and polyethylene glycol.

The tablets are gluten free.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

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