

APO-Donepezil Tablets

Contains the active ingredient donepezil hydrochloride (as monohydrate)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about donepezil. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO- Donepezil. It contains the active ingredient donepezil hydrochloride (as monohydrate).

It is used to treat mild, moderate and severe Alzheimer's disease, also called dementia of the Alzheimer's type.

This medicine will not cure this disease, but it should help your memory and improve your ability to think more clearly.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

There is no evidence that this medicine is addictive.

How it works

This medicine 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.

Use in children

Do not give this medicine to children.

There is not enough information to recommend using this medicine in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- You have had an allergic reaction to donepezil, piperidine derivatives or any of the ingredients listed at the end of this leaflet.

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

If you think you are having an allergic reaction, contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - heart problems
 - stomach problems, particularly gastric or duodenal ulcer
 - seizures or fits (epilepsy)
 - asthma or obstructive lung (pulmonary) disease

- loss of memory or other mental capacity due to a stroke or blood vessel problems
 - a tendency towards aggressive behaviour.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
 4. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
 5. You are planning to have surgery or an anaesthetic.
Donepezil may interfere with some of the medicines given during an operation.
 6. You are currently receiving or are planning to receive dental treatment.
 7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

If you have not told your doctor about any of the above, tell them before you take this medicine.

Taking other medicines

Some medicines and donepezil may interfere with each other. These include:

- any other medicine for dementia
- 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

- some medicines used to treat high blood pressure or fast heart beat
- some medicines used to treat irregular heart beat such as quinidine
- some medicines for treating asthma, diarrhoea, depression, schizophrenia and related mental conditions or used in general anaesthesia
- carbamazepine, phenobarbitone or phenytoin, medicines used to treat epilepsy
- ketoconazole, a medicine used to treat fungal infections
- rifampicin, an antibiotic used to treat tuberculosis
- dexamethasone, a corticosteroid medicine.

These medicines may be affected by donepezil or may affect the way donepezil works. You may need different amounts of your medicines, or may need to take different medicines.

Other medicines not listed above may also interact with donepezil.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take this medicine

Follow carefully all directions given to you by your doctor carefully.

Their instructions may be different to the information in this leaflet.

If you are not sure how to take this medicine, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines. The usual starting dose is one 5 mg tablet each day. After one month, your

doctor will assess your response and may increase your dose to one 10 mg tablet each day.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Always swallow the tablets whole with a full glass of water.

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

Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it

Continue taking this medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

It may take several weeks for this medicine to take effect, so do not be discouraged if you do not see an improvement straight away.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time.

Otherwise take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of unwanted side effects.

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

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

While you are taking this medicine

Things you must do

- If you become pregnant while you are using this medicine, tell your doctor.
- Tell all doctors, dentists and pharmacists who are treating you that you are using this medicine.
- If you are about to be started on any new medicine, tell your doctor or pharmacist that you are using this medicine.
- If you are about to have any blood tests.
- If you are going to have surgery, inform your doctor and tell the surgeon or anaesthetist that you are using this medicine.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

This medicine 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.

In addition, 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.

Please talk to your doctor or pharmacist about any concerns you may have about the above.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.

It can be difficult to tell whether side effects are the result of taking this medicine, the effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

Your doctor will decide whether any change in your treatment is needed.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Tell your doctor if you notice any of the following:

- heartburn, indigestion, or stomach pain
- headache, dizziness
- difficulty in sleeping
- unusual tiredness
- feeling sick, diarrhoea, vomiting,
- loss of appetite, weight loss
- bruising
- muscle cramps, joint pain
- tingling or numbness of the hands or feet
- depression, unusual dreams
- agitation, aggressive behaviour
- passing urine more often.

These are all mild side effects of donepezil.

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.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

- any breathing problems
- fainting, especially if you have a slow or irregular heart beat
- vomiting blood or material that looks like coffee grounds
- black sticky bowel motions (stools)
- convulsions or fits
- weakness, shortness of breath, yellowing of the skin, dark brown urine and stomach pain
- sudden increase in body temperature, sweating, muscle stiffness, or altered consciousness

(awareness of oneself and ones surrounding).

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

These side effects are very rare.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Other side effects not listed above may above may occur in some people. Tell your doctor if you notice any other side effects.

Allergic reactions

If you think you are having an allergic reaction to this medicine, tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hayfever-like symptoms

Storage and disposal

Storage

Keep your tablets in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your tablets in a cool dry place where the temperature will stay below 30°C.

Do not store your medicine, 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 this medicine 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

If your doctor or pharmacist tells you to stop taking this medicine or they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Donepezil looks like

APO-Donepezil 5 mg tablet - white to off-white, film coated circular, biconvex tablet with 'C' embossed on one side and '7' on the other.

APO-Donepezil 10 mg tablet - light yellow to yellow, film coated circular, biconvex tablet with 'C' embossed on one side and '6' on the other.

Ingredients

Each tablet contains 5 mg or 10 mg of donepezil hydrochloride as the active ingredient.

It also contains the following inactive ingredients:

- lactose monohydrate
- maize starch
- microcrystalline cellulose
- hypromellose
- sodium stearyl fumarate
- purified talc
- macrogol 6000
- hypromellose
- titanium dioxide
- iron oxide yellow (10mg tablet)

APO-Donepezil contains sugars as lactose. This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

APO-Donepezil is available in:
Blister packs of 28 tablets.

* Not all strengths may be available.

Australian Registration Numbers

New formulation

APO-Donepezil 5 mg tablet (blister pack): AUST R 213495.

APO-Donepezil 10 mg tablet (blister pack): AUST R 213496.

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

APO and APOTEX are registered trade marks of Apotex Inc.

This leaflet was prepared in October 2021.