

Donepezil Sandoz™

donepezil hydrochloride monohydrate film-coated tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Donepezil Sandoz.

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 this medicine 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 Donepezil Sandoz is used for

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

It contains the active ingredient donepezil hydrochloride monohydrate.

Donepezil hydrochloride belongs to a group of medicines called acetylcholinesterase inhibitors.

It is thought to work by increasing the level of a chemical called acetylcholine in the brain.

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

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

Before you take Donepezil Sandoz

When you must not take it

Do not take this medicine if you have an allergy to:

- donepezil hydrochloride, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product description
- piperidine derivatives
- any other similar medicines.

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 this medicine to children.

Safety and effectiveness 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.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

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

Tell your doctor if you have or have had any of the following medical conditions:

- heart problems
- stomach problems, particularly gastric or duodenal ulcer
- seizures or fits (epilepsy)
- asthma or obstructive pulmonary disease
- loss of memory or other mental capacity due to a stroke or blood vessel problems
- a tendency towards aggressive behaviour.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Donepezil Sandoz.

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 and Donepezil Sandoz may interfere with each other. These include:

- any other medicines used to treat 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 Sandoz or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

How to take Donepezil Sandoz

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

They may differ from the information contained in this leaflet.

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

How much to take

The usual starting dose is one 5mg tablet each day.

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

However, depending on your condition and how you react to Donepezil Sandoz, your doctor may prescribe a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Donepezil Sandoz may not work as well and your problem may not improve.

How to take it

Swallow the tablets whole with a full glass of water.

When to take Donepezil Sandoz

Take your medicine every night just before you go to bed.

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

Donepezil Sandoz can be taken with or without food.

How long to take Donepezil Sandoz

Continue taking your 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 Donepezil Sandoz to take effect, so do not be discouraged if you do not see an improvement straight away.

If you forget to take it

If you forget to take a tablet, just take one tablet the following day at the usual time, then continue as normal.

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, speak to 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.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Donepezil Sandoz. 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 heart beat, 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 Donepezil Sandoz

Things you must do

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

Donepezil Sandoz contains lactose.

If you have been told by your doctor that you have intolerance to some sugars, tell your doctor before taking it.

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 this medicine.

It may affect other medicines used during 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 take Donepezil Sandoz to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Donepezil Sandoz affects you.

This medicine may cause fatigue, dizziness and muscle cramps especially at the start of the 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.

Side effects

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

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:

- heartburn, indigestion, or stomach pain
- headache, dizziness
- difficulty sleeping, unusual tiredness

- feeling sick, diarrhoea, vomiting
- loss of appetite, weight loss
- bruising
- muscle cramps, joint pain
- temporary paralysis or weakness of muscles
- tingling or numbness of the hands or feet
- depression, unusual dreams
- agitation, aggressive behaviour
- difficulty in urinating or passing urine more often.

These are mild side effects of the medicine, and are usually 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.

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

- any breathing problems
- sudden signs of allergy 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 (stools)
- 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.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking Donepezil Sandoz

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

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

Do not store Donepezil Sandoz 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

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 it looks like

Donepezil Sandoz comes in two types of tablets:

Donepezil Sandoz 5mg - white, round film-coated tablet without score line.

Donepezil Sandoz 10mg - yellow, round film-coated tablet with one score line.

Available in blisters of 28 tablets.

Ingredients

Active ingredients:

- Donepezil Sandoz 5mg - 5mg donepezil hydrochloride as monohydrate
- Donepezil Sandoz 10mg - 10mg donepezil hydrochloride as monohydrate

Inactive ingredients:

- lactose
- maize starch
- microcrystalline cellulose
- magnesium stearate
- polyvinyl alcohol
- purified talc
- titanium dioxide
- macrogol 3350
- lecithin
- iron oxide yellow (10mg tablets only).

This medicine does not contain, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Donepezil Sandoz is supplied in Australia by:

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road,
Macquarie Park, NSW 2113
Tel: 1800 634 500

Novartis New Zealand Ltd
Private Bag 65904 Mairangi Bay
Auckland 0754
New Zealand
Tel: 0800 354 335

This leaflet was prepared in April 2016

Australian Register Numbers

5mg film-coated tablets: AUST R 157842 (blisters)

10mg film-coated tablets: AUST R 157837 (blisters)