

DONEPEZIL GH

(donepezil hydrochloride (as monohydrate)) film-coated tablet

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Donepezil GH. 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 Donepezil GH 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 GH is used for

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

Donepezil GH will not cure this disease but should help your memory and improve your ability to think more clearly.

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.

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 only available with a doctor's prescription.

Use in Children

Donepezil GH is not recommended for use in children.

The safety and effectiveness of Donepezil GH in children has not been established.

Before you take Donepezil GH

When you must not take it

Do not take Donepezil GH 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 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 be taking Donepezil GH, 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 plan to go to hospital for surgery that requires a general anaesthetic.

Donepezil GH may interfere with some of the medicines given during an operation.

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

- heart problems (such as irregular or very slow heartbeat, heart failure, myocardial infarction)
- a heart condition called 'prolonged QT interval' or a history of certain abnormal heart rhythms called Torsade de Pointes or if anyone in your family have 'prolonged QT interval'
- low levels of magnesium or potassium in your blood,
- stomach problems, particularly gastric or duodenal ulcer;
- seizures or fits;
- asthma or obstructive lung disease;
- loss of memory or other mental capacity due to stroke or blood vessel problems;
- tendencies toward aggressive behaviour.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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

If you have not told your doctor about any of the above, tell them before you start taking Donepezil GH.

Taking other medicines

Tell your doctor if you are taking any other medicines, including:

- all prescription medicines;
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by Donepezil GH 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 will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- any other medicine for dementia;
- medicines used to relieve stomach cramps or spasms, Parkinson's disease or travel sickness;
- medicines used to treat difficulty in passing urine;
- medicines used to treat arthritis, pain or inflammation known as non-steroidal anti-inflammatory drugs (NSAIDs);
- medicines used to relax muscles;
- medicines used in general anaesthesia
- medicines used to treat high blood pressure or fast heartbeat;
- medicines used to treat irregular heart beat such as quinidine;

- medicines for treating asthma, diarrhoea, depression, schizophrenia and related mental conditions, or used in general anaesthesia;
- medicines used to treat epilepsy - carbamazepine, phenobarbitone or phenytoin;
- ketoconazole, a medicine used to treat fungal infections;
- rifampicin, an antibiotic used to treat tuberculosis;
- dexamethasone, a corticosteroid medicine.
- Medicines for bacterial infections eg. clarithromycin, erythromycin, levofloxacin, moxifloxacin, rifampicin
- Medicines for heart rhythm problems e.g. amiodarone, sotalol
- Medicines for depression eg citalopram, escitalopram, amitriptyline, fluoxetine
- Medicines for psychosis eg pimozide, sertindole, ziprasidone

If you are not sure if you are taking any of these medicines, ask your doctor or pharmacist.

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

How to take Donepezil GH

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

They may differ from the information contained in this leaflet.

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

How much to take

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

After 1 month, your doctor will assess your response and may increase your dose to one Donepezil GH 10 mg tablet each day.

However, depending on your condition and how you react to the medicine, your doctor may ask you to take a different dose.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

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 GH can be taken with or without food.

How long to take it

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 your medicine 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 you missed.

This may increase the chance of you getting an unwanted side effect.

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

If you forget to take your medicine for more than 1 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)

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

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;
- slow heart beat;
- feeling dizzy or faint;
- difficulty breathing;
- seizures or fits;
- feeling weak;
- unable to control your bowel motions or passing of urine (incontinence).

While you are taking Donepezil GH

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 GH.

Tell all 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 this medicine to treat any other complaints unless your doctor says to.

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

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

Things to be careful of

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

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

Side effects

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

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.

It can be difficult to tell whether side effects are the result of taking Donepezil GH, 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.

Do not be alarmed by the following list 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 if...

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

- heartburn, indigestion, or stomach pain;
- headache or 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;
- difficulty in urinating or passing urine more often.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if...

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.
- Changes in the heart activity which can be seen on an electro-cardiogram (ECG) called 'prolonged QT interval'
- fast irregular heartbeat, fainting which could be the symptoms of a life

threatening condition known as Torsade de Pointes

The above list includes serious side effects which may require medical attention.

Go to hospital if...

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- any breathing difficulties;
- 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, 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.

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 GH

Storage

Keep your tablets in their blister pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

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

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

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 left over.

Product description

What it looks like

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

Donepezil GH 10 mg tablets are yellow, circular, biconvex, film-coated tablets, embossed with 'C' on one side and '6' on the other side.

Donepezil GH is supplied in blister packs of 28 tablets.

Ingredients

Active Ingredients

Each Donepezil GH tablet contains 5 mg or 10 mg donepezil hydrochloride (as monohydrate).

Inactive Ingredients

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

Donepezil GH tablets do not contain gluten.

Australian Registration Numbers

Donepezil GH 5 mg: AUST R 193661

Donepezil GH 10 mg: AUST R 193667

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