

Donepezil-DRLA tablets

Donepezil hydrochloride monohydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Donepezil-DRLA. 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-DRLA against the benefits they expect it will have for you.

If you have any concern about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Donepezil-DRLA is used for

Donepezil-DRLA Tablets are used to treat mild, moderate and severe Alzheimer's disease, also called dementia of the Alzheimer's type.

Donepezil-DRLA 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.

Before you take Donepezil-DRLA

When you must not take it

Do not take Donepezil-DRLA if you have an allergy to:

- Any medicine containing donepezil hydrochloride monohydrate
- 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 Donepezil-DRLA to children.

The safety and effectiveness of Donepezil-DRLA 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 be taking Donepezil-DRLA, 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-DRLA 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
- Stomach problems, particularly gastric or duodenal ulcers
- Seizures or fits (epilepsy)
- Asthma or obstructive lung disease
- Loss of memory or other mental capacity due to stroke or blood vessel problems
- A tendency towards 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 him/her before you start taking Donepezil-DRLA.

Taking other medicines

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

Some medicines and Donepezil-DRLA may interfere with each other. These include:

- any other medicine for dementia
- some medications 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-DRLA 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 Donepezil-DRLA.

If you have not told your doctor or pharmacist about these things, tell them before you start taking Donepezil-DRLA.

How to take Donepezil-DRLA

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-DRLA is one 5 mg tablet each day.

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

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

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

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

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

Donepezil-DRLA 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 Donepezil-DRLA 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 it 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 – the telephone number in Australia is 13 11 26 and in New Zealand is 0800 POISON or 0800 764 766 or go to Accident and Emergency (Causality) at your nearest hospital, if you think that you or anyone else may have taken too much Donepezil-DRLA. 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-DRLA

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking Donepezil-DRLA.

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

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. Your doctor may ask you to stop taking Donepezil-DRLA a few days before you have surgery.

Tell your doctor immediately if you become pregnant while taking Donepezil-DRLA.

If you are a woman of child-bearing age, you should avoid becoming pregnant while taking Donepezil-DRLA.

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 this medicine to anyone else, even if they have the same condition as you.

Do not use Donepezil-DRLA to treat any other complaint unless your doctor says to.

Things to be careful of

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

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.

Side Effects

Tell your doctor as soon as possible if you do not feel well while you are using Donepezil-DRLA.

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, but most of the time they are not. You may need medical treatment 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 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 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 which 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 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-DRLA

Storage

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.

Keep Donepezil-DRLA tablets in a cool, dry place where the

temperature stays below 30 degrees 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 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.

Disposal

If your doctor tells you to stop taking Donepezil-DRLA, or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.

Product Description

What it looks like

- Donepezil-DRLA 5 mg tablets: White, round, biconvex, film coated tablets debossed 'DNP' on one side and '5' on the other side.
- Donepezil-DRLA 10 mg tablets: Yellow, round, biconvex, film coated tablets debossed 'DNP' on one side and '10' on the other side.

Pack sizes are cartons of 14* or 28 tablets and HDPE bottles of 14*, 28*, 30*, 56*, 98*, 100* or 120* tablets.

Ingredients

- Active ingredients:
 - Donepezil-DRLA 5 mg – donepezil hydrochloride monohydrate equivalent to 5mg of donepezil hydrochloride/tablet
 - Donepezil-DRLA 10 mg – donepezil hydrochloride monohydrate equivalent to 10mg of donepezil hydrochloride/tablet
- The inactive ingredients include:
 - lactose monohydrate
 - pregelatinised maize starch

- hypollose
- microcrystalline cellulose
- magnesium stearate
- Tablets are film-coated & the coating for each tablet strength contains hypromellose 5 cP and titanium dioxide (E171)
- The following strengths also contain:
 - 5mg – macrogol 400
 - 10mg – macrogol 400 and iron oxide yellow (E172)

Sponsor

Donepezil-DRLA is supplied in Australia by:

Dr Reddy's Laboratories (Australia) Pty Ltd
Level 9, 492 St Kilda Road
Melbourne, VIC, 3004

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Australian Registration number.

Donepezil-DRLA tablets:

5 mg Blister AUST R 157106

5 mg Bottle AUST R 157120*

10 mg Blister AUST R 157133

10 mg Bottle AUST R 157137*

* Not available