

ARAZIL

Donepezil hydrochloride

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about ARAZIL

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking ARAZIL against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What ARAZIL is used for

ARAZIL tablets are used to treat mild, moderate and severe Alzheimer's disease, also called dementia of the Alzheimer's type.

ARAZIL will not cure this disease, but should help your memory and improve your thinking capacity.

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 ARAZIL

When you must not take it

Do not take ARAZIL if you have an allergy to:

- any medicine containing donepezil hydrochloride
- piperidine derivatives
- any of the ingredients listed at the end of the 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 ARAZIL to children.

Do not take this medicine if you are pregnant unless advised by your doctor.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

The active ingredient in ARAZIL passes into breast milk and there is a possibility that your baby may be affected.

The safety and effectiveness of ARAZIL 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 plan to go to hospital for surgery that requires a general anaesthetic.

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 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 ARAZIL.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other

medicines, including any that you get without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and ARAZIL 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, phenobarbital (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 ARAZIL 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 ARAZIL.

How to take ARAZIL

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 ARAZIL 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.

Do not divide the tablet into halves.

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 effect. It will also help you remember when to take it.

ARAZIL can be taken with or without food.

How long to take it

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

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 ARAZIL to take effect, so do not be discouraged if you do not see an improvement straight away.

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 Australian Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much ARAZIL. 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 ARAZIL

Tell all doctor, dentists and pharmacists who are treating you that you are taking ARAZIL.

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

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 ARAZIL a few days before you have surgery.

Tell your doctor immediately if you become pregnant while taking ARAZIL.

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

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 ARAZIL to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how ARAZIL 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 taking ARAZIL.

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:

- 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 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, 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 hospitalization.

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 ARAZIL

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 ARAZIL in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medication 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 origin 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 ARAZIL, or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

ARAZIL 5 mg tablets - 7 mm white, film coated, round tablets embossed with "DL over 5" on one side and "G" on the reverse.

ARAZIL 10 mg tablets - 9 mm white, film coated, round tablets embossed with "DL over 10" on one side and "G" on the reverse.

ARAZIL is available in either blister packs or bottle containing a pack size of 28 tablets.

Active ingredients

ARAZIL 5 mg - 5 mg donepezil hydrochloride/tablet. (Each tablet contains 4.56 mg donepezil)

ARAZIL 10 mg - 10 mg donepezil hydrochloride/tablet. (Each tablet contains 9.12 mg donepezil)

Other ingredients

The tablets also contain the following inactive ingredients:

- lactose monohydrate
- maize starch
- Hyprolose

- microcrystalline cellulose
- magnesium stearate
- Opadry white Y-1-7000 (ID no. 1475)

Supplier

ARAZIL is supplied by:

Alphapharm Pty Limited

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

ARAZIL 5 mg tablet blister pack

- AUST R 167692

ARAZIL 5 mg tablet bottle

- AUST R 167695

ARAZIL 10 mg tablet blister pack

- AUST R 167693

ARAZIL 10 mg tablet bottle

- AUST R 167694

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