

ARIDON

contains the active ingredient donepezil hydrochloride (as monohydrate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ARIDON.

It does not contain all of 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 ARIDON against the benefits they expect it will have 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 ARIDON is used for

ARIDON is used to treat Alzheimer's Disease, also called dementia of the Alzheimer's type.

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

ARIDON 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.

Your doctor may have prescribed ARIDON for another reason. Ask your doctor if you have any questions about why ARIDON has been prescribed for you.

ARIDON is available only with a doctor's prescription.

There is no evidence that ARIDON is addictive.

Before you take ARIDON

When you must not take it

Do not take ARIDON if you are allergic to medicines containing donepezil hydrochloride, piperidine derivatives or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

Do not give ARIDON to children.

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

Do not take ARIDON if the expiry date (Exp.) printed on the pack has passed.

Do not take ARIDON if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

Your doctor will discuss the risks and benefits of taking ARIDON during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Your doctor will discuss the risks and benefits of taking ARIDON when breastfeeding.

Tell your doctor if 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 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 plan to have surgery that requires a general anaesthetic.

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

Taking other medicines

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

Some medicines may be affected by ARIDON, or may affect how well it works. 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.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take ARIDON

How much to take

The usual starting dose for ARIDON 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.

Depending on your condition and how you react to the medicine, your doctor may advise you to take a different dose.

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

How to take ARIDON

Swallow the tablets with a glass of water.

Take ARIDON 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.

If you forget to take ARIDON

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.

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.

How long to take ARIDON for

Keep taking ARIDON for as long as your doctor recommends.

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

If you take too much ARIDON (overdose)

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

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking ARIDON.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking ARIDON.

If you become pregnant while taking ARIDON, tell your doctor immediately.

If you are a female of child-bearing age, you should avoid getting pregnant while taking ARIDON.

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking ARIDON.

ARIDON may affect other medicines used during surgery. Your doctor may ask that you stop taking ARIDON for a few days before you have surgery.

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 use ARIDON to treat any other conditions unless your doctor tells you to.

Do not give ARIDON 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 ARIDON affects you.

ARIDON may cause fatigue, dizziness and muscle cramps, especially at the start of treatment or when the dosage is increased. If any of these occur, 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 or pharmacist as soon as possible if you do not feel well while you are taking ARIDON.

Like all other medicines, ARIDON may have unwanted side effects in some people. Sometimes they are serious, 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 this list of possible 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 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:

- include serious but not life-threatening side effects
- 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.

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

- include serious and life-threatening
- 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.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using ARIDON

Storage

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

Do not store ARIDON or any other medicine in the bathroom or near a sink.

Do not leave ARIDON in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking ARIDON, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

ARIDON comes in 2 strengths of tablets:

- ARIDON 5 - round white tablet marked DE 5 on one side and the Arrow logo on the other
- ARIDON 10 - round yellow tablet marked DE 10 on one side and the Arrow logo on the other.

Each pack contains 28 tablets.

Ingredients

The active ingredient in ARIDON is donepezil hydrochloride (as monohydrate):

- each ARIDON 5 tablet contains 5 mg of donepezil hydrochloride (as monohydrate) (equivalent to 4.56 mg of donepezil)
- each ARIDON 10 tablet contains 10 mg of donepezil hydrochloride (as monohydrate) (equivalent to 9.12 mg of donepezil).

The tablets also contain:

- mannitol
- crystalline sorbitol
- crospovidone
- colloidal anhydrous silica
- sodium stearyl fumarate
- Opadry II 85F18378 White (5 mg tablets only, Proprietary ingredient no. 12135)
- Opadry II 85F62663 Yellow (10 mg tablets only, Proprietary ingredient no. 12432).

The tablets are lactose and gluten free.

Supplier

ASPEN PHARMA PTY LTD

34-36 Chandos Street,
St. Leonards NSW 2065
Australia

Australian registration numbers:

ARIDON 5 - AUST R 175983
ARIDON 10 - AUST R 175987

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