

Arimac 5 (Donepezil HCL Tablets 5mg)

Arimac 10 (Donepezil HCL Tablets 10mg)

Donepezil Hydrochloride (5mg & 10mg)

What is in this leaflet

1. What Arimac is used for
2. How Arimac works
3. Before you use Arimac
4. How to use Arimac
5. While you are using it
6. Side effects
7. Storage and Disposal of Arimac
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

What is Arimac used for

Arimac is used for the symptomatic treatment of mild, moderate & severe dementia in Alzheimer's disease.

How Arimac works

Arimac is one of a group of medicines called acetylcholinesterase inhibitor. It increases the levels of a substance (acetylcholine) in the brain involved in memory function by slowing down the breakdown of acetylcholine.

Before you use Arimac

-When you must not use it

If you are allergic to donepezil hydrochloride or to piperidine derivatives, or any of the other ingredients of Arimac. If you are in any doubt at all, consult your doctor before taking donepezil.

-Before you start to use it

Talk to your doctor before taking Arimac if you:

- Develop stomach or duodenal ulcers.
- Seizures (fits) or convulsions.
- A heart condition (irregular or very slow heart beat)
- Asthma or other long term lung disease.

- Liver problems or hepatitis.
- Difficulty passing urine or mild kidney disease.
- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.
- If you are taking Arimac, you should not breast-feed

Children and Adolescents: Arimac is not recommended for use in children.

Tell the doctor about all your present or past health problems. Including:

- Any heart problems including problems with irregular, slow or fast heartbeats.
- 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.

-Taking other medications

Some other medicines may influence the use of donepezil or vice versa. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

- Other Alzheimer's disease medicines, e.g. galantamine.
- Pain killers or treatment for arthritis, e.g. aspirin, non-steroidal anti-inflammatory (NSAIDs) drugs such as ibuprofen or diclofenac sodium.
- Anticholinergics medicines, e.g. tolterodine.
- Antibiotics, e.g. erythromycin, rifampicin.
- Muscle relaxants, e.g. diazepam, succinylcholine.
- General anaesthetics.

If you get any unusual symptoms taking any of these medicines together with Arimac, you should see your doctor.

Be particularly sure to tell the doctor if you are taking any of the following types of medicines:

- Medicines for heart rhythm problems e.g. amiodarone, sotalol and quinidine.
- Medicines for depression e.g. citalopram, escitalopram, amitriptyline.
- Medicines for psychosis e.g. pimozide, sertindole, ziprasidone.
- Medicines for bacterial infections e.g. clarithromycin, erythromycin, levofloxacin, moxifloxacin.

How to use Arimac

-How much to use

Usually, you will start by taking 5 mg every night. After one month, your doctor may tell you to take 10 mg every night. Swallow your Arimac tablet with a drink of water before you go to bed at night. The tablet strength you will take may change depending on the length of time you have been taking the medicine and on what your doctor recommends. The maximum recommended dose is 10 mg each night. Always follow your doctor's, or pharmacist's advice about how and when to take your medicine. Do not alter the dose yourself without your doctor's advice.

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

You should take donepezil for as long as your doctor continues to prescribe it.

Arimac 5 (Donepezil HCL Tablets 5mg)

Arimac 10 (Donepezil HCL Tablets 10mg)

Donepezil Hydrochloride (5mg & 10mg)

-If you forget to use it

If you forget to take a dose of donepezil, take your tablet straightaway and then take your next tablet at the usual time. If it is already near to your next dosing, skip the missing dose and do not take a double dose to make up for a forgotten tablet dose.

-If you use too much (overdose)

Symptoms of overdosing include feeling and being sick, drooling, sweating, slow heart rate, low blood pressure (lightheadedness or dizziness when standing), breathing problems, losing consciousness and seizures (fits) or convulsions.

Contact your doctor or the nearest emergency department if you experience such symptoms.

While you are using it

-Things you must do

Follow your doctor's instructions carefully. Do not increase your dose or use this drug more often than prescribed.

You should tell your doctor or pharmacist if you notice any side effects not listed in the see 'Possible side effects' section of this leaflet or if you notice that a side effect gets serious.

Try to take the Arimac tablet at the same time each day.

It does not matter whether you take it with or without food.

Always take the tablet with water and swallow it whole.

-Things you must not do

Do not alter or discontinue the daily dose without first consulting your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Arimac to anyone else, even if they have the same symptoms or condition as you.

Avoid drinking alcohol while taking donepezil.

-Things to be careful of

Do not drive or operate a machine until you know how Arimac affects you.

Side effects

Like all medicines, donepezil can cause side effects, although not everybody gets them. Contact your doctor immediately if you experience:

- Diarrhoea & muscle cramps.
- Fatigue, nausea, vomiting, insomnia & dizziness.
- Psychiatric disturbances, including hallucinations, agitation, aggressive behaviours.

Unknown (frequency cannot be estimated):

- Fast, irregular heart beat and fainting, which could be symptoms of a life-threatening condition known as Torsade de Pointes.
- Changes in the heart activity which can be seen on an electrocardiogram (ECG) called 'prolonged QT interval'.

If any of the side effects get serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of product name

-Storage

Store below 30°C in a dry place and protect from light. Keep out of reach of children.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

Arimac 5: White to off white, round shaped, biconvex, film coated tablets debossed with "ML 89" on one side and plain on the other side.

Arimac 10: Yellow colour, round shaped, biconvex, film coated tablet debossed "ML 88" on one side and plain on the other side.

-Ingredients

☐ Active ingredient(s)

Donepezil Hydrochloride.

☐ Inactive ingredient(s)

Colloidal silicon dioxide, lactose monohydrate, microcrystalline cellulose (PH 102), pre-gelatinized starch, magnesium stearate and purified water.

Coating material: Opadry white 02H58708 for Arimac5 and Opadry yellow 02H82475 for Arimac 10.

Arimac 5 (Donepezil HCL Tablets 5mg)

Arimac 10 (Donepezil HCL Tablets 10mg)

Donepezil Hydrochloride (5mg & 10mg)

-MAL number

Arimac 5: MAL19051002AZ

Arimac 10: MAL19051003AZ

Manufacturer:

Macleods Pharmaceuticals Ltd.

Block N-2, Village Theda, Post Office

Lodhimajra, Tehsil Baddi,

District Solan, Himachal Pradesh,

174101, India.

Product Registration Holder:

Macleods Pharmaceuticals Sdn. Bhd.

A2-27-1 Soho Suites KLCC,

Jalan Perak, 50450 Kuala Lumpur,

Malaysia.

Date of revision

24/04/2025

Serial Number

NPRA(R2/1)230323/1033