

ALZER 10 (Donepezil Hydrochloride Tablets 10mg)

(Donepezil Hydrochloride tablets 5mg/ Donepezil Hydrochloride tablets 10mg)

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What ALZER 5 / ALZER 10 is used for

Donepezil Tablets contains a medicine called Donepezil Hydrochloride. This belongs to a group of medicines called acetylcholinesterase inhibitors.

It is used to treat the symptoms of dementia in people diagnosed as having mild, moderate and severe Alzheimer's disease. The symptoms include increasing memory loss, confusion and behavioural changes.

As a result, sufferers of Alzheimer's disease find it more and more difficult to carry out their normal daily activities.

How ALZER 5 / ALZER 10 works

Donepezil increases the levels of a substance (acetylcholine) in the brain involved in memory function by slowing down the breakdown of acetylcholine

Before you use ALZER 5 / ALZER 10

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.

When you must not use it

Do not take Donepezil Tablets

If you are allergic (hypersensitive) to donepezil hydrochloride or any of the other ingredients of Donepezil Tablets.

Take special care with Donepezil Tablets

Tell your doctor or pharmacist before starting to take Donepezil Tablets if you have or have had:

- 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

Also tell your doctor if you are pregnant or think you might be pregnant.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicine. This includes medicines that your doctor has not prescribed for you but which you have bought yourself from a chemist/pharmacist. It also applies to medicines you may take sometime in the future if you continue to take Donepezil Tablets. This is because these medicines may weaken or strengthen the effects of Donepezil Tablets. 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.
- Anticholinergics medicines, e.g. Tolterodine
- Antibiotics e.g. Erythromycin, Rifampicin
- Anti-fungal medicine e.g. Ketoconazole
- Anti-depressants e.g. Fluoxetine
- Anticonvulsants e.g. Phenytoin, Carbamazepine
- Medication for a heart condition e.g. Quinidine, beta-blockers (Propranolol and Atenolol)
- Muscle relaxants, eg Succinylcholine
- Medicines obtained without a prescription e.g. Herbal remedies

If you are going to have an operation that requires you to have a general anaesthetic, you should tell your doctor and the anaesthetist that you are taking Donepezil Tablets. This is because your medicine may affect the amount of anaesthetic needed.

Donepezil Tablets can be used in patients with kidney disease or mild to moderate liver disease. Tell your doctor first if you have kidney or liver disease. There are no data for patients with severe hepatic impairment.

Tell your doctor or pharmacist the name of your caregiver. Your caregiver will help you to take your medicine as it is prescribed.

Pregnancy

If you are pregnant, or think you might be pregnant, ask your doctor for advice before taking any medicine.

Breast-feeding

Donepezil Tablets should not be used while breastfeeding.

How to use ALZER 5 / ALZER 10

How much to use

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 label, ask your doctor or pharmacist for help.

How much to take

Mild to Moderate Alzheimer's Disease

Treatment is initiated at 5mg/day (once-a-day dosing). Donepezil should be taken orally, in the evening, just prior to retiring. The 5mg/day dose should be maintained for at least one month in order to allow the earliest clinical responses to treatment to be assessed and

to allow steady-state concentrations of donepezil hydrochloride to be achieved.

Following a 4 to 6 weeks of clinical assessment in patients who tolerated treatment at 5mg/day, the dose of Donepezil can be increased to 10mg/day (once-a-day dosing). The

maximum recommended daily dose is 10mg.

Severe Alzheimer's Disease

Donepezil is effective at a dose of 10mg administered once daily.

However steady state is not achieved for 15 days and because the incidence of untoward effects may be influenced by the rate of dose escalation, a dose of 10mg should not be escalated until patients have been on a daily dose of 5mg for 4 to 6 weeks.

Upon discontinuation of treatment, a gradual abatement of the beneficial effects of Donepezil is seen. There is no evidence of a rebound effect after abrupt discontinuation of therapy.

Renal and hepatic impairment

A similar dose schedule can be followed for patients with renal impairment as clearance of donepezil hydrochloride is not affected by this condition.

Children

Donepezil is not recommended for use in children.

When to take it

- Take your tablet with or without food
- Take your tablets at about the same time each day.

How long to take it

Your doctor or pharmacist will advise you on how long you should continue to take your tablets. You will need to see your doctor from time to time to review your treatment and assess your symptoms.

If you forget to take it

If you forget to take a tablet, just take one tablet the following day at the usual time. Do not take a double dose to make up for a forgotten tablet.

If you forget to take your medicine for more than one week, call your doctor before taking any more medicine.

If you take too much (overdose)

If you take more than you should, contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Always take Donepezil exactly as your doctor has told you.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not alter the dose yourself without your doctor's advice.
- Do not stop the treatment unless your doctor tells you otherwise.

- Things to be careful of

Driving and using machines

Alzheimer's disease may impair your ability to drive or operate machinery and you must not perform these activities unless your doctor tells you that it is safe to do so.

Also, your medicine can cause tiredness, dizziness and muscle cramp. If you experience any of these effects, you must not drive or operate machinery.

Side effects

Like all medicines, **ALZER 5 / ALZER 10** can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Some side effects can be serious and need immediate medical attention:

You should see your doctor immediately if you experience any of the following symptoms:

- Cardiovascular: 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'.
 - hypertension, rare cases of angina, slow heart rate, atrioventricular block (blockage in the heart), sino-atrial block (delay, or absence of atrial response),
- Endocrine metabolic: weight decreased, loss of appetite
- Gastrointestinal: diarrhoea, loss of appetite, nausea, vomiting, gastrointestinal hemorrhage, abdominal pain, flatulence, gastric and duodenal ulcers
- Blood: contusion (bruises), bluish area on the skin
- Skin: rash, itchiness,
- Hepatic: Increased liver enzymes (transaminases), liver dysfunction including hepatitis
- Musculoskeletal: muscle cramps, increased enzyme (creatin kinase) level
- Neurologic: weak, dizziness, headache, difficulty sleeping, sleepy, seizures, fainting, extrapyramidal symptoms
- Psychiatric: depression, dream disorder, hallucinations, agitation, aggressive behaviour, confusion

- Renal and urinary disorders: urinary incontinence, urinary-tract infections
- Other: fatigue, upper-respiratory-tract infections, sweating

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 ALZER 5 / ALZER 10

- Storage

Store below 30°C

- 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*

Donepezil Hydrochloride Tablets 5 mg:

White to off white round biconvex, film coated tablets debossed with '1' on one side and '24' on the other side.

Donepezil Hydrochloride Tablets 10 mg:

Yellow round biconvex, film coated tablets debossed with '1' on one side and '21' on the other side.

- *Ingredients*

Active Ingredients

Donepezil Hydrochloride

Inactive Ingredients

Lactose monohydrate,
Microcrystalline cellulose,
Corn starch, Hydroxypropyl
cellulose, Purified water,

Magnesium stearate, Opadry
white/ Opadry yellow

- MAL number(s):

Donepezil Hydrochloride 5mg :

MAL17035036AZ

Donepezil Hydrochloride 10mg:

MAL17035031AZ

Manufacturer

Hetero Labs Limited
Unit-V, Sy.No. 439,440,441 & 458
TSIIC Formulation SEZ, Polepally
Village, Jadcherla Mandal,
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Product Registration Holder

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