

JUBDOZIL Tablet

Donepezil hydrochloride 5mg
Donepezil hydrochloride 10mg

What is in this leaflet

1. What is JUBDOZIL Tablet used for
2. How JUBDOZIL Tablet works
3. Before you use JUBDOZIL Tablet
4. How to use JUBDOZIL Tablet
5. While you are using JUBDOZIL Tablet
6. Side Effects
7. Storage and Disposal of JUBDOZIL Tablet
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

1. What JUBDOZIL Tablet is used for

JUBDOZIL Tablet is used for the symptomatic treatment of mild to moderately severe Alzheimer's dementia.

2. How JUBDOZIL Tablet works

Donepezil hydrochloride belongs to a group of medicines called acetylcholinesterase inhibitors.

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

3. Before you use JUBDOZIL Tablets

When you must not use it

- If you are allergic (hypersensitive) to donepezil hydrochloride, to related substances (piperidine derivatives) or to any of the

other ingredients of donepezil hydrochloride.

- During pregnancy and breast feeding.
- In children under 18 years of age.

Before you start to use it

Follow all instructions given to you by your doctor carefully, even if they differ from the information contained in this leaflet.

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 hydrochloride. This is because these medicines may weaken or strengthen the effects of donepezil hydrochloride.

Especially tell your doctor if you are taking any of the following types of medicines:

- Other Alzheimer's disease medicines, e.g. galantamine
- Pain killers or treatment for arthritis e.g. aspirin, non-steroidal anti-inflammatory (NSAID) drugs such as ibuprofen, or diclofenac sodium
- 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 e.g. diazepam, succinylcholine
- General anaesthetic
- 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 hydrochloride. This is because your medicine may affect the amount of anaesthetic needed.

Donepezil hydrochloride 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. Patients with severe liver disease should not take donepezil hydrochloride. Tell your doctor or pharmacist the name of your caregiver. Your caregiver will help you to take your medicine as it is prescribed.

4. How to use JUBDOZIL Tablet

How much to use

Usually, you will start by taking 5 mg (one white to off-white tablet) every night. After one month, your doctor may tell you to take 10 mg (one white to off-white tablet) every 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.

JUBDOZIL Tablet

Donepezil hydrochloride 5mg
Donepezil hydrochloride 10mg

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

Swallow your JUBDOZIL Tablet with a drink of water before you go to bed at night.

How long to use 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 use 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 use too much (overdose)

DO NOT take more than one tablet each day. Call your doctor immediately if you take more than you should. If you cannot contact your doctor, contact the local hospital Accident and Emergency department at once. Always take the tablets and the carton with you to the hospital so that the doctor knows what has been taken.

Symptoms of overdosing include feeling and being sick, drooling, sweating, slow heart rate, low blood pressure (light-headedness or dizziness when standing), breathing problems, losing consciousness and

seizures (fits) or convulsions.

5. While you are using JUBDOZIL Tablet

Things you must do

Follow all instructions given to you by your doctor carefully, even if they differ from the information contained in this leaflet.

Things you must not do

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.

Things to be careful of

Tell your doctor or pharmacist before starting to take Donepezil hydrochloride 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.

6. Side Effects

You must tell your doctor immediately if you notice these side effects mentioned. You may

need urgent medical treatment.

Cardiovascular: hypertension, rare cases of angina, heart condition (irregular or very slow heart beat)

Endocrine metabolic: weight decreased, anorexia

Gastrointestinal: diarrhoea, loss of appetite, nausea, vomiting, gastrointestinal bleeding, abdominal pain, indigestion, stomach and duodenal ulcers

Blood: bruises

Skin: rash, itchiness,

Liver: Increased liver enzymes, liver problems including hepatitis (symptoms of hepatitis includes feeling or being sick, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes)

Musculoskeletal: muscle cramps, muscle stiffness

Neurologic: feeling weak, dizziness, headache, difficulty in sleeping, drowsiness, seizures (fits) or convulsions, fainting, shaking or uncontrollable movement

Mental disorder: depression, unusual dreams including nightmares, hallucinations (seeing or hearing things that are not really there), agitation, aggressive behaviour, confusion

Renal and urinary disorders: passing urine uncontrollably, urinary-tract infections

Other: tiredness, upper-respiratory-tract infections (common cold), sweating

JUBDOZIL Tablet

Donepezil hydrochloride 5mg
Donepezil hydrochloride 10mg

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

7. Storage and Disposal of JUBDOZIL Tablet

Storage

DO NOT use JUBDOZIL Tablet after the expiry date that is printed on the label. The expiry date refers to the last day of that month.

This medicinal product should store below 30°C. Keep out of the reach of children.

If your doctor tells you to stop taking your medicine, you should return any you have not used to your pharmacist.

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.

8. Product Description ***What it looks like***

JUBDOZIL 5mg Tablet

White to off-white, round, film-coated Tablets, debossed with 'J' on one side and '5' on the other.

JUBDOZIL 10mg Tablet

White to off-white, round, film-coated Tablets, debossed with 'J' on one side and '10' on the other.

Ingredients

- Active ingredient: Donepezil hydrochloride

- Inactive ingredients:

Lactose monohydrate, Cellulose microcrystalline, Maize Starch, Low substituted hydroxypropyl cellulose, Magnesium Stearate, Hypromellose, Macrogol, Talc, Titanium Dioxide, Purified

water.

MAL number:

JUBDOZIL 5mg
Tablet:
MAL16045033AZ
JUBDOZIL 10mg
Tablet:
MAL16045034AZ

9. Manufacturer and Product Registration Holder

Manufacturer

Jubilant Generics Ltd.,
Village Sikandarpur Bhainswal,
Roorkee- Dehradun Highway,
Bhagwanpur, Roorkee,
District Haridwar, Uttarakhand
247 661,
India

Product Registration Holder

SYNERRV SDN BHD,
SO-29-2, MENARA 1, KL ECO
CITY,
JALAN BANGSAR, KG HAJI
ABDULLAH HUKUM,
59200 KUALA LUMPUR,
MALAYSIA.

10. Date of Revision

30/11/2020

Serial Number

NPRA(R2/1)201127/568