

DONAZET[®]

DESCRIPTION

DONAZET is the trademark of Donepezil Hydrochloride, belongs to a group of medicines called acetylcholinesterase inhibitors and is used to treat the symptoms of dementia in people diagnosed as having mild and moderately severe Alzheimer's disease.

Each **DONAZET 5** Film Coated Tablet contains 5mg Donepezil Hydrochloride.

Each **DONAZET 10** Film Coated Tablet contains 10mg Donepezil Hydrochloride.

Excipients: lactose monohydrate, cellulose microcrystalline, maize starch, hydroxypropyl cellulose, magnesium stearate, hypromellose, macrogol, talc, titanium dioxide.

CHEMISTRY

Donepezil Hydrochloride: (±)-2-[(1-Benzyl-4-piperidyl)methyl]-5,6-dimethoxy-1-indanone hydrochloride.

CLINICAL PHARMACOLOGY

Donepezil hydrochloride is a specific and reversible inhibitor of acetylcholinesterase, the predominant cholinesterase in the brain. Donepezil hydrochloride is *in vitro* over 1000 times more potent an inhibitor of this enzyme than of butyrylcholinesterase, an enzyme that is present mainly outside the central nervous system. It is approximately 95% bound to human plasma proteins.

Donepezil hydrochloride is both excreted in the urine intact and metabolised by the cytochrome P450 system to multiple metabolites, not all of which have been identified. Plasma donepezil concentrations decline with a half-life of approximately 70 hours.

INDICATIONS

It is used to treat the symptoms of dementia in people diagnosed as having mild and moderately 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.

DOSAGE

Usually, you will start by taking 5 mg (one **DONAZET 5** Tablet) every night. After one month, your doctor may tell you to take 10 mg (one **DONAZET 10**) every night.

Notes:

Swallow your **DONAZET** tablet with a drink of water before you go to bed at night. Food will not influence the effect of **DONAZET**.

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.

ADVERSE EFFECTS

Serious side effects:

You must tell your doctor immediately if you notice these serious side effects mentioned. You may need urgent medical treatment.

liver damage e.g. hepatitis. The symptoms of hepatitis are feeling or being sick, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes and dark coloured urine (probably affecting fewer than 1 in 1,000).

stomach or duodenal ulcers. The symptoms of ulcers are stomach pain and discomfort (indigestion) felt between the navel and the breast bone (probably affecting fewer than 1 in 100).

bleeding in the stomach or intestines. This may cause you to pass black tar like stools or visible blood from the rectum (probably affecting fewer than 1 in 100).

seizures (fits) or convulsions (probably affecting fewer than 1 in 100).

Very common side effects (probably affecting more than 1 in 10):

- diarrhoea
- feeling or being sick.
- headaches.

Common side effects (probably affecting up to 1 in 10):

- muscle cramp.
- tiredness.
- difficulty in sleeping (insomnia).
- the common cold.
- loss of appetite.
- hallucinations (seeing or hearing things that are not really there).
- agitation.
- aggressive behaviour.
- fainting.
- dizziness.
- stomach feeling uncomfortable.
- rash.
- itching.
- passing urine uncontrollably.
- pain.
- accidents (patients may be more prone to falls and accidental injury).

Uncommon side effects (probably affecting fewer than 1 in 100):

slow heart beat
Rare side effects (probably affecting fewer than 1 in 1,000):

stiffness, shaking or uncontrollable movement especially of the face and tongue but also of the limbs.

USE IN PREGNANCY

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

USE IN LACTATION

Donepezil must not be used while breastfeeding.

DRUG INTERACTIONS

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

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.
- anticholinergic 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. This is because your medicine may affect the amount of anaesthetic needed.

Donepezil 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.

CONTRAINDICATIONS

DO NOT take Donepezil:

- if you are allergic (hypersensitive) to donepezil hydrochloride or to piperidine derivatives or any of the other ingredients of Donepezil.
- if you are breast feeding.

WARNINGS

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.

OVERDOSE

DO NOT take more than one tablet each day. Call your doctor immediately if you take more than you should take.

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.

PRECAUTIONS

Tell your doctor or pharmacist before starting to take Donepezil 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.

HOW SUPPLIED

- Boxes of 30 blistered tablets of **DONAZET 5**.
 - Boxes of 30 blistered tablets of **DONAZET 10**.
 - Hospital packs of different presentations.
- Store according to conditions specified on the package.
Do not use after the expiry date shown on the package.

THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
- The doctor and the pharmacist are experts in medicine.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicaments out of the reach of children.

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COUNCIL OF ARAB HEALTH MINISTERS
UNION OF ARAB PHARMACISTS

Prescribing Information Available Upon Request



Manufactured by: Jubilant Life Sciences Ltd. - India

Product license holder: The Jordanian Pharmaceutical Manufacturing CO. (P.L.C.) / P.O. Box 94, Na'ur 11710, Jordan