

Dozept 5 mg Film-Coated Tablets
Dozept 10 mg Film-Coated Tablets

donepezil hydrochloride



Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1. What Dozept is and what it is used for
- 2. What do you need to know before you take Dozept
- 3. How to take Dozept
- 4. Possible side effects
- 5. How to store Dozept
- 6. Contents of the pack and other information

1 What Dozept is and what it is used for

Dozept 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.

Dozept is used to treat the **symptoms of dementia** in people diagnosed as having mild to 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

Dozept film-coated tablets are for use in adult patients only.

2 What do you need to know before you take Dozept

Do not take this medicine if you are **allergic** to

- donepezil hydrochloride or
- piperidine derivatives, which are similar substances to donepezil, or
- soya, peanut or any of the other ingredients of Dozept film-coated tablets as (listed in section 6)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Dozept film-coated tablets.

If any of the following concerns you, you or your caregiver should **inform your doctor or pharmacist**.

- 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.

Other medicines and Dozept film-coated tablets
Tell your doctor or pharmacist if you are taking, have recently taken or **might take any other medicines**.

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 Dozept film-coated tablets. This is because these medicines may weaken or strengthen the effects of Dozept film-coated tablets.

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 (propanolol 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 Dozept film-coated tablets. This is because your medicine may affect the amount of anaesthetic needed.

Dozept film-coated 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. Patients with severe liver disease should not take Dozept film-coated tablets.

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

Dozept film-coated tablets with food, drink and alcohol

Food will not influence the effect of Dozept film-coated tablets. Dozept film-coated tablets should not be taken with alcohol because alcohol may change their effect.

Pregnancy, breast-feeding and fertility
Dozept film-coated tablets should not be used while breastfeeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Alzheimer’s disease may impair your ability to drive or operate machines. Do not perform these activities unless your doctor has confirmed that this is safe. This medicine can cause fatigue, dizziness and muscle cramps particularly during the beginning of therapy and dose increase. If affected you must not drive or operate machines.

Dozept film-coated tablets contain lactose and maize starch
Dozept film-coated tablets contain lactose and maize starch (source of glucose). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3 How to take Dozept

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The usual dose is:

Adults and elderly patients
for 5 mg tablets

- **Starting dose:** 1 film-coated tablet every night
- **After one month:** possible increase to 2 film-coated tablets every night.
- **Maximum dose:** 2 film-coated tablets every night

for 10 mg tablets

- **Starting dose:** ½ film-coated tablet every night
- **After one month:** possible increase to 1 film-coated tablet every night.
- **Maximum dose:** 1 film-coated tablet every night

Do not alter the dose yourself without your doctor’s advice.

Patients with kidney dysfunction
You can take the usual dose as described above. No adjustment is required.

Patients with mild to moderate liver dysfunction
Your doctor will check your tolerance to Dozept film-coated tablets before increasing the dose.

Patients with severe liver dysfunction
Your doctor will decide if Dozept film-coated tablets is suitable for you.

Method of administration
Take your film-coated tablets at night before you go to bed, independently from meals. Swallow the film-coated tablets with a glass of water.

Duration of use
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 take more Dozept film-coated tablets than you should
DO NOT take more than 10 mg Donepezil hydrochloride 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.

If you forget to take Dozept film-coated tablets
If you forget to take a film-coated tablet, just take one film-coated tablet the following day at the usual time. Do not take a double dose to make up for a forgotten dose. If you forget to take your medicine for more than one week, call your doctor before taking any more medicine.

If you stop taking Dozept film-coated tablets
Do not stop taking this medicine unless instructed by your doctor. Positive treatment results may gradually diminish if treatment is stopped.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported by people taking Dozept film-coated tablets. Tell your doctor if you have any of these effects while you are taking Dozept film-coated tablets.

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 (affects 1 to 10 users in 10,000).
- stomach or duodenal ulcers. The symptoms of ulcers are stomach pain and discomfort (indigestion) felt between the navel and the breast bone (affects 1 to 10 users in 1,000).
- bleeding in the stomach or intestines. This may cause you to pass black tar like stools or visible blood from the rectum (affects 1 to 10 users in 1,000).
- seizures (fits) or convulsions (affects 1 to 10 users in 1,000).
- fever with muscle stiffness, sweating or a lowered level of consciousness (a disorder called “Neuroleptic Malignant Syndrome”) (affects less than 1 user in 10,000).
- muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell, have a high temperature or have dark urine. They may be caused by an abnormal muscle breakdown which can be life threatening and lead to kidney problems (a condition called rhabdomyolysis).

Reported side effects listed according to the frequencies are:

Very common, may affect more than 1 in 10 people:

- diarrhoea
- nausea
- headache

Common, may affect 1 to 10 users in 100:

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

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Uncommon, may affect up to 1 in 100 people:

- slow heart beat

Rare, may affect up to 1 in 1,000 people

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Dozept film-coated tablets

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister or on the label of the plastic-bottle. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not use this medicine after 6 months have elapsed from first opening of the plastic-bottle.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Dozept film-coated tablets contains

The active substance is donepezil hydrochloride.

Each film-coated tablet contains 5 mg of donepezil hydrochloride.

Each film-coated tablet contains 10 mg of donepezil hydrochloride.

The other ingredients are:

Tablet core:

Microcrystalline cellulose

Lactose monohydrate

Maize starch

Magnesium stearate

Tablet coat:

<5 mg:>

polyvinyl alcohol

talc

titanium dioxide (E 171)

macrogol 3350

soya lecithin

<10 mg:>

polyvinyl alcohol

talc

titanium dioxide (E 171)

macrogol 3350

soya lecithin

iron oxide yellow (E 172).

What Dozept film-coated tablets look like and contents of the pack

Dozept 5 mg film-coated tablets are white and round (diameter 7 mm).

Dozept 10 mg film-coated tablets are yellow and round (diameter 9 mm) with score line. They can be divided into equal doses.

Dozept film-coated tablets is available in

- blisters
 - Pack sizes of 7, 10, 14, 28, 30, 50, 56, 60, 84, 90, 98, 100, 100x1 or 120 film-coated tablets
- plastic-bottles with a screw cap
 - Pack sizes of 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Salutas Pharma GmbH, Dieselstrasse 5, 70839 Gerlingen, Germany.

Lek S.A., ul. Domaniewska 50 C, 02-672 Warszawa, Poland.

S.C. Sandoz S.R.L. Targu Mures, Romania.

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

Lek S.A., Ul. Podlipie 16, 95-010 Strykow, Poland.

This medicinal product is authorised in the Member States of the EEA under the following names:

Germany:

Donepezil-HCl HEXAL 5 mg Filmtabletten

Donepezil-HCl HEXAL 10 mg Filmtabletten

Ireland:

Dozept 5 mg Film-Coated Tablets

Dozept 10 mg Film-Coated Tablets

United Kingdom:

Donepezil Hydrochloride 5 mg Film-coated Tablets

Donepezil Hydrochloride 10 mg Film-coated Tablets

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