

Package leaflet: Information for the patient

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 Dozept

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 this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Dozept.

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 (such as irregular or very slow heartbeat, heart failure, myocardial infarction)
- 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
- asthma or other long term lung disease
- liver problems or hepatitis

- difficulty passing urine or mild kidney disease
- any involuntary or abnormal movements of the tongue, face or body (extrapyramidal symptoms).
Dozept may induce or exacerbate extrapyramidal symptoms.

Dozept 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.

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

Other medicines and Dozept

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

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
- medicines for bacterial infections (such as clarithromycin, erythromycin, levofloxacin, moxifloxacin, rifampicin)
- anti-fungal medicine e.g. ketoconazole
- medicines for depression (e.g. citalopram, escitalopram, amitriptyline, fluoxetine)
- medicines for psychoses (e.g. pimozide, sertindole, ziprasidone)
- anticonvulsants e.g. phenytoin, carbamazepine
- medicines for heart rhythm problems (e.g. amiodarone, sotalol)
- 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 Dozept. This is because your medicine may affect the amount of anaesthetic needed.

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

Dozept with food, drink and alcohol

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

Pregnancy, breast-feeding and fertility

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.

- **You should not take** Dozept if you are pregnant unless your doctor decides that it is clearly necessary.
Inform your doctor immediately if you are pregnant or think you may be pregnant.
- **You should not breast-feed** while taking Dozept.

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 contains lactose and maize starch

Dozept contains 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 before increasing the dose.

Patients with severe liver dysfunction

Your doctor will decide if Dozept 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.

<for 10 mg tablets only>

The tablet can be divided into equal doses.

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 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

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

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. Tell your doctor if you have any of these effects while you are taking Dozept.

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 (may affect up to 1 in 1,000 people).
- stomach or duodenal ulcers. The symptoms of ulcers are stomach pain and discomfort (indigestion) felt between the navel and the breast bone (may affect up to 1 in 100 people).
- bleeding in the stomach or intestines. This may cause you to pass black tar like stools or visible blood from the rectum (may affect up to 1 in 100 people).
- seizures (fits) or convulsions (may affect up to 1 in 100 people).
- fever with muscle stiffness, sweating or a lowered level of consciousness (a disorder called "Neuroleptic Malignant Syndrome") (may affect up to 1 in 10,000 people).
- 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 people:

- 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
- vomiting
- rash
- itching
- passing urine uncontrollably
- pain
- accident (patients may be more prone to falls and accidental injury).

Uncommon, may affect up to 1 in 100 people:

- slow heartbeat
- minor increase of the muscle enzyme creatine kinase in blood tests.

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
- changes in heart rhythm.

Frequency not known:

- changes in the heart activity which can be seen on an electro-cardiogram (ECG) called 'prolonged QT interval'
- fast, irregular heartbeat, fainting which could be symptoms of a life-threatening condition known as Torsade de Pointes.

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 the national reporting system: HPR A Pharmacovigilance; website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Dozept

Keep this medicine 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 after EXP. 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 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 (E171)

macrogol 3350

soya lecithin

<10 mg:>

polyvinyl alcohol

talc

titanium dioxide (E171)

macrogol 3350

soya lecithin

iron oxide yellow (E172).

What Dozept looks like and contents of the pack

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

Dozept 10 mg film-coated tablets are yellow and round (diameter approx. 9 mm) with score line.

Dozept 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.

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

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

Sandoz S.R.L., Str. Livezeni nr. 7A, 540472 Targu-Mures, Romania.

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

This leaflet was last revised in 12/2021.