Package leaflet: Information for the patient

Donepezil Sandoz 5 mg orodispersible tablets
Donepezil Sandoz 10 mg orodispersible 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 Donepezil Sandoz is and what it is used for

Donepezil Sandoz 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.
Donepezil Sandoz 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

Donepezil Sandoz is for use in adult patients only.

2. What you need to know before you take Donepezil Sandoz

Do not take Donepezil Sandoz
if you are **allergic** to
- donepezil hydrochloride or
- piperidine derivatives, which are similar substances to donepezil, 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 Donepezil Sandoz. 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 (Donepezil may have the potential to cause seizures).
- a heart condition (such as irregular or very slow heart beat, 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

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

Children and adolescents
Donepezil Sandoz is not recommended for use in children and adolescents (younger than 18 years of age).

Other medicines and Donepezil Sandoz

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 Donepezil Sandoz. This is because these medicines may weaken or strengthen the effects of Donepezil Sandoz
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 medicines 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 (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 Donepezil Sandoz. This is because your medicine may affect the amount of anaesthetic needed.
Donepezil Sandoz 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 Sandoz.

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

Donepezil Sandoz with food, drink and alkohol

Food will not influence the effect of Donepezil Sandoz.

Donepezil Sandoz should not be taken with alcohol because alcohol may change its effect.

Pregnancy, breast-feeding and fertility

Donepezil Sandoz 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.

Donepezil Sandoz contains aspartame and sodium
This medicine contains 8.4 mg aspartame in each orodispersible tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.
This medicine contains less than 1mmol (23 mg) sodium, that is so to say essentially "sodium-free".

3. How to take Donepezil Sandoz

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
5 mg orodispersible tablets:
- **Starting dose:** 1 orodispersible tablet every night
- **After one month:** possible increase to 2 orodispersible tablets every night.
- **Maximum dose:** 2 orodispersible tablets every night

10 mg orodispersible tablets:
- **Starting dose:** 5 mg every night, which can not be dosed using this medicinal product. Donepezil Sandoz are available to start treatment.
- **After one month:** possible increase to 1 orodispersible tablet every night.
- **Maximum dose:** 1 orodispersible 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 Donepezil Sandoz before increasing the dose.

Patients with severe liver dysfunction
Your doctor will decide if Donepezil Sandoz is suitable for you. *Patients with severe liver disease should not take Donepezil.*

Method of administration
Take your orodispersible tablets at night before you go to bed, independently from meals. Place them on your tongue and let them disintegrate before swollowing, with or without water, according to your preference.
If you experience abnormal dreams, nightmares or difficulty in sleeping (see section 4) your doctor may advise you to take Donepezil Sandoz in the morning.

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 Donepezil Sandoz 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 orodispersible tablets, this leaflet and/or 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 Donepezil Sandoz
If you forget to take an orodispersible tablet, just take one orodispersible 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 Donepezil Sandoz
Do not stop taking the orodispersible tablets unless instructed by your doctor. Positive treatment results may gradually diminish if treatment is stopped.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
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, These are the symptoms of 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) (may affect up to 1 in 10,000 people).

Other side effects that may occur:

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

- diarrhoea
- nausea (feeling sick)

- headache

Common, may affect up to 1 in 10 people
- muscle cramps
- tiredness
- difficulty in sleeping (insomnia)
- 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
- accidents (patients may be more prone to falls and accidental injury)

Uncommon, may affect up to 1 in 100 people
- slow heart beat
- minor increase of the muscle enzyme creatine kinase in blood tests
- salivary hypersecretion

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 heart beat, fainting which could be symptoms of a life-threatening condition known as Torsade de Pointes
- Libido increased, hypersexuality
- Pisa syndrome (a condition involving involuntary muscle contraction with abnormal bending of the body and head to one side)

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 listed in Appendix V*.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Donepezil Sandoz

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 Donepezil Sandoz contains

- The active substance is donepezil hydrochloride.
  Each orodispersible tablet contains 5 mg of donepezil hydrochloride.
  Each orodispersible tablet contains 10 mg of donepezil hydrochloride.

- *<5 mg:>*The other ingredients are aspartame (E 951), croscarmellose sodium, magnesium stearate, mannitol (E 421), microcrystalline cellulose, peppermint flavour, colloidal anhydrous silica, zinc sulfate monohydrate.

- *<10 mg:>* The other ingredients are aspartame (E 951), croscarmellose sodium, iron oxide yellow (E 172), magnesium stearate, mannitol (E 421), microcrystalline cellulose, peppermint flavour, colloidal anhydrous silica, zinc sulfate monohydrate.

What Donepezil Sandoz looks like and contents of the pack

5 mg orodispesible tablets:
White, round, flat with debossment “5” on one side and plain on the other side.

10 mg orodispesible tablets:
Yellow, slightly dotted, round, flat with debossment “10” on one side and plain on the other side.

The orodispersible tablets are packed in Alu/PVC/ACLAR blisters and inserted in a carton, or are packed in a HDPE-bottle with a PP screw cap.

Pack sizes:
Blister: 7, 10, 14, 28, 30, 50, 56, 60, 84, 90, 98, 120 orodispersible tablets
Bottle: 100 orodispersible tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:

[To be completed nationally]

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