Package leaflet: Information for the patient

Donepezil Hydrochloride 5 mg orodispersible tablets
Donepezil Hydrochloride 10 mg orodispersible tablets

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Donepezil Hydrochloride is and what it is used for
2. What you need to know before you take Donepezil Hydrochloride
3. How to take Donepezil Hydrochloride
4. Possible side effects
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1. What Donepezil Hydrochloride is and what it is used for

Donepezil Hydrochloride contains the active substance donepezil hydrochloride. Donepezil hydrochloride belongs to a group of medicines called acetylcholinesterase inhibitors. Donepezil hydrochloride increases the levels of a substance (acetylcholine) in the brain involved in memory function by slowing down the breakdown of that substance.

It is used to treat the symptoms of dementia in people diagnosed as having mild to moderately severe Alzheimer's disease. Symptoms of the illness include increasing memory loss, confusion and behavioural changes. As a result, sufferers of Alzheimer's disease find it more difficult to carry out their normal daily activities.

It is for use in adult patients only.

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

Do not take Donepezil Hydrochloride:
- if you are allergic to donepezil hydrochloride, or to piperidine derivatives, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Donepezil Hydrochloride if you have, or have had:
- Stomach or duodenal ulcers
- Seizures (fits) or convulsions
- 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 pregnant.

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

Other medicines and Donepezil Hydrochloride
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 some time in the future if you continue to take Donepezil Hydrochloride. This is because these medicines may weaken or strengthen the effects of Donepezil Hydrochloride.

In particular it is important to tell your doctor or pharmacist if you are taking any of the following types of medicines:

- medicines for heart rhythm problems e.g. amiodarone, sotalol
- medicines for depression e.g. citalopram, escitalopram, amitriptyline, fluoxetine
- medicines for psychosis e.g. pimozide, sertindole, ziprasidone
- medicines for bacterial infections e.g. clarithromycin, erythromycin, levofloxacin, moxifloxacin, rifampicin
- antifungal medicines e.g. ketoconazole
- other Alzheimer's disease medicines e.g. galantamine
- anticonvulsants e.g. carbamazepine, phenytoin
- medication for a heart condition e.g. quinidine, beta blockers (propranolol and atenolol)
- general anaesthetic
- pain killers or treatment for arthritis e.g. aspirin, non steroidal anti-inflammatory drugs (NSAID) such as ibuprofen or diclofenac sodium
- muscle relaxants e.g. diazepam, succinylcholine
- medicines obtained without a prescription e.g. herbal remedies
- anticholinergics medicines e.g. tolterodine

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.

Donepezil Hydrochloride with food, drink and alcohol

Food will not influence the effect of Donepezil Hydrochloride.
Donepezil Hydrochloride should not be taken with alcohol because alcohol may change its effect.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Donepezil Hydrochloride should not be used while breast-feeding.

Driving and using machines

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

Donepezil Hydrochloride contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Donepezil Hydrochloride

How much Donepezil Hydrochloride should you take

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Initially, the recommended dose is 5 mg (one white tablet) every night before you go to bed. After one month, your doctor may tell you to take 10 mg (one yellow tablet) every night before you go to bed. If you experience abnormal dreams, nightmares or difficulty in sleeping (see section 4) your doctor may advise you to take Donepezil in the morning.
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.
Always follow your doctor or pharmacist's advice about how and when to take your medicine.
Do not alter the dose yourself without your doctor's advice.

How to take your medicine
The tablet should be placed on your tongue and allowed to disintegrate before swallowing, with or without water, according to your preference.

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

If you take more Donepezil Hydrochloride than you should
Contact your doctor or nearest hospital emergency department immediately if you take more of the medicine than you should. Take this leaflet and any remaining tablets with you.

Overdose symptoms may include nausea (feeling sick) and vomiting (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 Hydrochloride
If you forget to take your medicine, take the next dose 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 stop taking Donepezil Hydrochloride

Do not stop taking your tablets unless told to do so by your doctor. If you stop taking Donepezil Hydrochloride, the benefits of your treatment will gradually fade away.

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

For how long should you take Donepezil Hydrochloride
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.

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 Donepezil Hydrochloride.

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

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 nausea (feeling sick) or vomiting (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) (may affect up to 1 in 10,000 people)
- fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as Torsade de Pointes (frequency cannot be estimated from the available data)

Other side effects:

Very common side effects (may affect more than 1 in 10 people):
- diarrhoea
- headache.

Common side effects (may affect up to 1 in 10 people):
- muscle cramps
- tiredness
- difficulty in sleeping (insomnia)
- common cold

- hallucinations (seeing or hearing things that are not really there)
- unusual dreams including nightmares
- agitation
- aggressive behaviour
- fainting
- dizziness
- stomach feeling uncomfortable rash
- passing urine uncontrollably
- pain
- accidents (patients may be more prone to falls and accidental injury).

Uncommon side effects (may affect up to 1 in 100 people):
- slow heartbeat
- saliva hypersecretion

Rare side effects (may affect up to 1 in 1,000 people):
- stiffness, shaking or uncontrollable movement especially of the face and tongue but also of the limbs.

Not known (frequency cannot be estimated from the available data):
- changes in the heart activity which can be seen on an electro-cardiogram (ECG) called 'prolonged QT interval'
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Donepezil Hydrochloride

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date, which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

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 Hydrochloride contains:

- The active substance is donepezil hydrochloride.
- Donepezil Hydrochloride 5 mg orodispersible tablets: Each tablet contains 5 mg donepezil hydrochloride (equivalent to 4.56 mg donepezil).

- Donepezil Hydrochloride 10 mg orodispersible tablets: Each tablet contains 10 mg donepezil hydrochloride (equivalent to 9.12 mg donepezil).

The other ingredients are mannitol (E421); colloidal anhydrous silica; hydroxypropylcellulose; acesulfame potassium; glycine; sodium starch glycolate; crospovidone (Type A); microcrystalline cellulose; and magnesium stearate.

Donepezil Hydrochloride 10 mg orodispersible tablets also contain yellow iron oxide (E172).

What Donepezil Hydrochloride looks like and contents of the pack

Your medicine is in the form of an orodispersible tablet.

Donepezil Hydrochloride 5 mg orodispersible tablets are white coloured round flat bevelled edged tablets, marked with “DL 5” on one side and “M” on the other side.

Donepezil Hydrochloride 10 mg orodispersible tablets are yellow coloured round flat bevelled edged tablets, debossed with “DL 10” on one side and “M” on the other side.

Donepezil Hydrochloride 5 mg and 10 mg orodispersible tablets are available in blister packs of 7, 10, 14, 28, 30, 50, 56, 60, 84, 98, 100, 120 or 180 orodispersible tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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