Package leaflet: Information for the patient

Donepezil hydrochloride 5 mg Film-coated tablets
Donepezil hydrochloride 10 mg Film-coated tablets

The medicine will be referred to as Donepezil tablets throughout the remainder of the leaflet

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 tablets are and what they are used for

Donepezil tablets contain the active substance donepezil hydrochloride and belong 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.

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.

Donepezil tablets are for use in adult patients only.

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

Do not take Donepezil tablets

- if you are allergic to donepezil hydrochloride, or to piperidine derivatives, or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include rash, itching, swelling of face, lips, or hands/feet, or breathing difficulties.

Warnings and precautions

Talk to your doctor or pharmacist before taking Donepezil tablets 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. Donepezil tablets can be used in patients with mild to moderate liver disease. Patients with severe liver disease should not take Donepezil tablets.
- difficulty passing urine or kidney disease. However, Donepezil tablets can be used in patients with kidney disease.
- any involuntary or abnormal movements of the tongue, face or body (extrapyramidal symptoms). Donepezil may induce or exacerbate extrapyramidal symptoms.

Children and adolescents

Donepezil tablets are not recommended for use in children and adolescents.

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

In particular it is important to tell your doctor 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 psychoses, e.g. pimozide, sertindole, ziprasidone
- medicines for bacterial infections, e.g. clarithromycin, erythromycin, levofloxacin, moxifloxacin, rifampicin
- anti-fungal medicines, e.g. ketoconazole
- other Alzheimer’s disease medicines, e.g. galantamine
- pain killers or treatment for arthritis e.g. acetylsalicylic acid, non-steroidal anti-inflammatory (NSAID) drugs such as ibuprofen, or diclofenac sodium
- anticholinergics medicines, e.g. tolterodine
- 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 medicines

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 tablets. 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 prescribed.

Donepezil tablets with food, drink and alcohol

Food will not influence the effect of Donepezil tablets.

Donepezil tablets should not be taken with alcohol because alcohol may reduce its 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.

Donepezil tablets 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 tablets contain lactose and sodium

Donepezil tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

3. How to take Donepezil tablets

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

How much Donepezil tablets should you take?

Initially, the recommended dose is 5 mg of donepezil hydrochloride every night.

If you experience abnormal dreams, nightmares or difficulty in sleeping (see section 4) your doctor may advise you to take donepezil in the morning.

After one month, your doctor may tell you to take 10 mg of donepezil hydrochloride every night.

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's or pharmacist's advice about how and when to take your medicine.

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

Use in children and adolescents

This medicine is not recommended for use in children and adolescents younger than 18 years of age.

Taking your medicine

Oral use.
Swallow your Donepezil tablet with a drink of water before you go to bed at night.

If you take more Donepezil tablets than you should

Contact your doctor or the 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 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 tablets

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 tablets

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

For how long should you take Donepezil tablets?

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 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.

The following side effects have been reported by people taking Donepezil tablets.

Tell your doctor if you have any of these effects while you are taking Donepezil tablet(s)

Serious side effects

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

Uncommon (may affect up to 1 in 100 people):
• Seizures (fits) or convulsions
• Stomach or duodenal ulcers. The symptoms of ulcers are stomach pain and discomfort (indigestion) felt between the navel and the breast bone
• Bleeding in the stomach or intestines. This may cause you to pass black tar like stools or visible blood from the rectum

Rare (may affect up to 1 in 1000 people):
• Slow heart rate associated with dizziness, weakness, confusion
• 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

Very rare (may affect up to 1 in 10,000 people):
• Fever with muscle stiffness, sweating or a lowered level of consciousness (a disorder called "Neuroleptic Malignant Syndrome")
• 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)

Not known (frequency cannot be estimated from available data)
- 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

Other side effects

Very common: may affect more than 1 in 10 people
• diarrhoea
• feeling sick
• headaches

Common: may affect up to 1 in 10 people
• muscle cramp
• tiredness
• difficulty in sleeping (insomnia)
• the common cold
• loss of appetite (anorexia)
• hallucinations (seeing or hearing things that are not really there)
• unusual dreams including nightmares
• agitation
• aggressive behaviour
• fainting
• dizziness
• stomach feeling uncomfortable, being sick (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 in serum concentration of muscle creatine kinase
• salivary hypersecretion

Rare: 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 available data)
- 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Donepezil tablets

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 blister and carton 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 tablets contains
The active substance is donepezil hydrochloride:

5 mg
Each tablet contains 5 mg donepezil hydrochloride, equivalent to 4.56 mg of donepezil.

10 mg
Each tablet contains 10 mg donepezil hydrochloride, equivalent to 9.12 mg donepezil.

The other ingredients are:
Core- Lactose monohydrate, Maize starch, Hydroxypropyl cellulose, Microcrystalline cellulose, Sodium starch glycolate (type A), Magnesium stearate.
Coating- Opadry yellow contains Hypromellose 5cP (E464), Titanium dioxide (E171), Macrogol 400, Talc, Iron Oxide Yellow (E172)

What Donepezil tablets look like and contents of the pack

Donepezil hydrochloride 5 mg Film-coated tablets are yellow coloured, circular, biconvex film-coated tablets debossed with ‘RC25’ on one side

Donepezil hydrochloride 10 mg Film-coated tablets are yellow coloured, capsule shaped film-coated tablets debossed with ‘RC’ & ‘26’ on either side of the score line.
The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Product is available in blister packs of:

5 mg: 7, 28, 30, 56, 98, and 100 film-coated tablets

10 mg: 28, 30, 56, 98, and 100 film-coated tablets
Not all pack sizes may be marketed.

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