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
5. How to store Donepezil Hydrochloride
6. Contents of the pack and other information

1. What Donepezil Hydrochloride is and what it is used for

Donepezil belongs to a group of medicines called acetylcholinesterase inhibitors.

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 is for use only in adult patients.

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

Do not take Donepezil Hydrochloride

- if you are allergic to donepezil hydrochloride, or piperidine derivatives, or to 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. In particular, tell your doctor:

- if you have or have had stomach or duodenal ulcers
- if you have or have had seizures (fits) or convulsions
- if you have or have had a heart condition (irregular or very slow heart beat)
- if you have or have had asthma or other long term lung disease
- if you have or have had liver problems or hepatitis
- if you have or have had difficulty passing urine or mild kidney disease

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.

Other medicines and Donepezil Hydrochloride

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking any of the following 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 Donepezil Hydrochloride. This is because your medicine may affect the amount of anaesthetic needed.

**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**
Donepezil Hydrochloride should not be used during pregnancy unless clearly necessary.

Donepezil Hydrochloride 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 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 lactose**
This medicine contains lactose. If you have been told by your doctor that you have intolerance to some sugars, you should contact your doctor before taking Donepezil Hydrochloride.

### 3. How to take Donepezil Hydrochloride

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

Usually, you will start by taking 5 mg (one white tablet) every night. After one month, your doctor may tell you to take 10 mg (one yellow tablet) every night.
Swallow your Donepezil Hydrochloride with a drink of water before you go to bed at 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.

**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.

**If you take more Donepezil Hydrochloride than you should**
Do not take more than one tablet 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 Donepezil Hydrochloride**
If you forget to take a tablet, just take one tablet the following day 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 the 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.

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.

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

**Other side effects that may occur:**

**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
- hallucinations (seeing or hearing things that are not really there)
- unusual dreams including 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 in serum concentration of muscle creatine kinase
- seizures (fits)
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
- disturbance in heart rhythm

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
Website: 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 Hydrochloride

- 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 after EXP. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- 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. Each film-coated tablet contains Donepezil hydrochloride monohydrate equivalent to donepezil hydrochloride 5 mg / 10 mg

The other ingredients are:
**Core:** Lactose monohydrate, maize starch, cellulose microcrystalline, low-substituted hydroxypropyl cellulose, magnesium stearate

**Coating:**
For 5 mg: Hypromellose (E464), titanium dioxide (E171), macrogol 400, talc (E553b)
For 10 mg: Hypromellose (E464), titanium dioxide (E171), macrogol 400, talc (E553b), iron oxide yellow (E172)

What Donepezil Hydrochloride looks like and contents of the pack
Donepezil Hydrochloride is presented as 5 mg, and 10 mg tablets. The tablets are described below.

5 mg: White to off-white, round, approximately 7.14 mm in diameter, bevelled edge, biconvex, film coated tablets with inscription "5" on one side and plain on other side.
10 mg: Yellow, round, approximately 8.73 mm in diameter, biconvex, film coated tablets with inscription "10" on one side and plain on other side.

Donepezil Hydrochloride 5 mg / 10 mg Tablets is available in the following pack sizes:

PVC/Alu Blister in outer carton: 7, 10, 28, 30, 50, 56, 60, 84, 98 and 120 tablets
HDPE Bottle: 100 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Accord Healthcare Limited,
Sage House, 319 Pinner Road,
North Harrow, Middlesex,
HA1 4HF, United Kingdom

Manufacturer
Accord Healthcare Limited,
Sage House, 319 Pinner Road,
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