PACKAGE LEAFLET: INFORMATION FOR THE USER

Donepezil hydrochloride 5 mg film-coated tablets
Donepezil hydrochloride 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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects gets 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

Donepezil hydrochloride 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 break down 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 hydrochloride 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, 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.

Tell your doctor or pharmacist before starting to take Donepezil hydrochloride if you have or have had:
- stomach or duodenal ulcers
- seizures (fits) or convulsions
- a heart condition (irregular or very slow heart beat)
- 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 children and adolescents below the age of 18 years.

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 sometime in the future if you continue to take Donepezil hydrochloride. This is because these medicines may weaken or strengthen the effects of Donepezil hydrochloride.

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
- 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 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 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 and breast-feeding
Donepezil hydrochloride should not be used while breastfeeding.
If you are pregnant, think you might 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.

Important information about some of the ingredients of Donepezil hydrochloride
This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, 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.

The recommended dose is
Usually, you will start by taking 5 mg donepezil hydrochloride every night. After one month, your doctor may tell you to take 10 mg donepezil hydrochloride every night.
Swallow your Donepezil hydrochloride tablet 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 donepezil hydrochloride 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.
The tablet can be divided into equal doses.

For how long should you take Donepezil hydrochloride?
Your doctor or pharmacist will adviseyou 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 tablets than you should. 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 product, 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 (affects 1 to 10 users in 10,000).
- stomach or duodenal ulcers. The symptoms of ulcers are stomach pain and discomfort (indigestion) felt between the navel and the breast bone (affects 1 to 10 users in 1,000).
- bleeding in the stomach or intestines. This may cause you to pass black tar like stools or visible blood from the rectum (affects 1 to 10 users in 1,000).
- seizures (fits) or convulsions (affects 1 to 10 users in 1,000).
- fever with muscle stiffness, sweating or a lowered level of consciousness (a disorder called "Neuroleptic Malignant Syndrome") (affects less than 1 user in 10,000).

Very common side effects (affects more than 1 user in 10):
- diarrhoea
- feeling or being sick
- headaches

Common side effects (affects 1 to 10 users in 100):
- 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
- rash
- itching
- passing urine uncontrollably
- pain
- accidents (patients may be more prone to falls and accidental injury)

Uncommon side effects (affects 1 to 10 users in 1,000):
- slow heart beat

Rare side effects (affects 1 to 10 users in 10,000):
- stiffness, shaking or uncontrollable movement especially of the face and tongue but also of the limbs

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 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, the blister or on the bottle after EXP. The expiry date refers to the last day of that month.
This medicinal product does not require any special storage conditions.

HDPE bottle:
The shelf life after first opening the bottle is 90 days.

Do not throw away any medicines via wastewater or householdwaste. Ask your pharmacist how to throw away medicines no longer use. These measures will help to 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
  Each film-coated tablet contains 5 mg donepezil hydrochloride, equivalent to 4.56 mg of donepezil.
  Donepezil hydrochloride 10 mg
  Each film-coated tablet contains 10 mg donepezil hydrochloride, equivalent to 9.12 mg of donepezil.
- The other ingredients are maize starch, lactose monohydrate, microcrystalline cellulose, magnesium stearate, in the tablet core, and hypromellose, macrogol 6000, talc and titanium dioxide (E171) in the film coating.
  Additional in Donepezil hydrochloride 10 mg: Ferric oxide yellow (E172) and ferric oxide red (E172)

What Donepezil hydrochloride looks like and contents of the pack

Donepezil hydrochloride 5 mg
White to off-white coloured, round, biconvex film coated tablets debossed with '5' on one side and break line on other side.

Donepezil hydrochloride 10 mg
Peach coloured, round, biconvex film coated tablets debossed with '10' on one side and break line on other side.

The tablets are supplied in
white bottles (HDPE) with child resistant closure , containing 28, 30, 56 or 98 (2 x 49) film-coated tablets or in
PVC/Alu Blister, containing 28, 30, 56, or 98 film-coated tablets or in
OPA/Alu/PVC/Alu Blister with 28, 30, 56, or 98 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Torrent Pharma (UK) Ltd.
Unit 4, Charlwood Court,
County Oak Way
Crawley
West Sussex. RH11 7XA
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Manufacturer
Torrent Pharma (UK) Ltd.
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This leaflet was last revised in 11/2014

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Pantone Reflex Blue

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LOCATION : Indrad	**COUNTRY : UK**	**Supersedes A/W No.:**		
SIZE : 160 x 350 mm_Front / Back Side		**CODE : 8052073-7803**	**DATE : 28-11-2014**	
REMARK : Folding Length 35 mm				
SUBSTRATE :				
Activities	**Department**	**Name**	**Signature**	**Date**
Prepared By	**Pkg.Dev**			
Reviewed By	**Pkg.Dev**			
Reviewed By	**RA**			
Approved By	**CQA**			

This colour proof is not colour binding. Follow Pantone shade reference for actual colour matching.

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