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 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 Hydrochloride is used for the treatment of dementia. 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 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, to piperidine derivatives medicines (your doctor or pharmacist can advise on this) 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 suffer or have ever suffered from any of the following conditions:

- heart rate or rhythm problem (e.g an irregular heart beat, sick sinus syndrome, or other conditions that affect the rate or rhythm of the heart). Donepezil Hydrochloride may slow down your heart rate
- stomach or duodenal (gut) ulcers
- difficulty in passing urine
- fits or seizures–Donepezil Hydrochloride may have the potential to cause fits or seizures. Your doctor will monitor your symptoms

Page 1 of 6
• stiffness, shaking or uncontrollable movement especially of the face and tongue but also of the limbs (which may have occurred after taking certain medicines and referred to ‘extrapyramidal’ or ‘Parkinson’s’ like effects)
• asthma or other long term lung problems
• liver problems.

**Children and adolescents**
Children and adolescents under the age of 18 years of age should not take this medicine.

**Other medicines and Donepezil Hydrochloride**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines taken without a prescription. In particular, tell your doctor or pharmacist if you are taking any of the following:

• other Alzheimer’s disease medicines e.g. galantamine
• antidepressants (e.g. fluoxetine)
• erythromycin (an antibiotic)
• rifampicin (for treatment of tuberculosis)
• antifungal medicines e.g. ketoconazole, itroconazole
• carbamazepine or phenytoin (for the control of epilepsy)
• medication for heart conditions e.g. quinidine, beta blockers (e.g. propanolol and atenolol)
• pain killers or treatment for arthritis e.g. acetylsalicylic acid (aspirin), non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, or diclofenac
• anticholinergics (medicines which typically cause dry mouth, blurred vision and/or drowsiness) e.g. tolterodine (used for bladder problems).

If you are going to have an operation, including dental surgery, that requires you to have an anaesthetic, tell your doctor, dentist, hospital staff or the anaesthetist that you are taking this medicine.

**Donepezil Hydrochloride with alcohol**

Take special care if drinking alcohol whilst taking this medicine as alcohol can reduce the effect of donepezil.

**Pregnancy and breast-feeding**

If you are pregnant, think you may be pregnant or are planning to have a baby, do not take this medicine before speaking to your doctor for advice. Donepezil should not be used in pregnancy unless clearly necessary.

Donepezil Hydrochloride should not be used while breast-feeding.

**Driving and using machines**

Do not drive or operate machinery if you feel dizzy, sleepy or get muscle cramps while taking this medicine. Alzheimer’s disease may also impair your ability to drive or operate machinery. You must not perform these activities unless your doctor tells you that it is safe to do so.

**Donepezil Hydrochloride contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
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.

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

**Adults**
The recommended starting dose is 5 mg of Donepezil Hydrochloride taken once a day for at least one month. Your doctor may increase this to 10 mg of Donepezil Hydrochloride taken once a day. The maximum recommended daily dose is 10 mg. If you experience an increase in side effects while taking 10 mg each day, tell your doctor or pharmacist.

**Use in patients with liver and kidney disease**
For adults with mild to moderate liver disease, your doctor may need to adjust your dose. No dosage adjustment is required if you have kidney problems.

**Method of administration**
Take your Donepezil Hydrochloride by mouth with a drink of water in the evening before you go to sleep.

Your doctor will advise you on how long you should continue to take your tablets. You will need to see your doctor regularly to review your treatment and assess your symptoms. You can take this medicine with or without food.

**If you take more Donepezil Hydrochloride than you should**

Do not take more than one tablet each day. Contact your doctor or nearest hospital casualty department immediately if you take more tablets than you should. Take the container and any remaining tablets with you to the hospital so the doctor knows what has been taken.

If you take more Donepezil Hydrochloride than you should, you might have symptoms such as feeling sick (nausea), being sick (vomiting), salivation, sweating, slow heart rate (bradycardia), low blood pressure (light-headedness or dizziness when standing), breathing problems, losing consciousness, convulsions (fits). You could also suffer from an increased muscle weakness which may be a life threatening condition if respiratory muscles are involved.

**If you forget to take Donepezil Hydrochloride**

If you forgot 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, contact your doctor before taking any more medicine.

**If you stop taking Donepezil Hydrochloride**

When treatment is stopped the beneficial effects of Donepezil Hydrochloride will decrease gradually.

Do not stop taking your tablets without first discussing with your doctor.

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.
Tell your doctor or go to the nearest hospital emergency department immediately if you notice any of the following serious side effects:

**Uncommon** (may affect up to 1 in 100 people)
- bleeding in the stomach, guts or bowel, or ulcers of the stomach or duodenum (gut). If you are sick you may notice fresh blood or coffee like grounds in the sick, or you may pass black tarry stools or fresh blood from the rectum (back passage)
- seizures (fits).

**Rare** (may affect up to 1 in 1,000 people)
- liver problems including hepatitis (inflammation of the liver). You may notice by dark urine, pale stools, yellowing of the skin and whites of the eyes (jaundice), feel sick and have a fever
- changes to your heart beat, such as changes to the rhythm, or ‘missed’ beats, which may be signs of problems with the electrical signals in your heart

**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)

**Other side effects include:**

**Very common** (may affect more than 1 in 10 people):
- diarrhoea
- feeling sick
- headache.

**Common** (may affect up to 1 in 10 people):
- being sick
- muscle cramps
- feeling tired
- insomnia (difficulty sleeping)
- common cold
- anorexia (loss of appetite)
- hallucinations (seeing or hearing things that are not real)
- unusual dreams including nightmares
- agitation
- aggressive behaviour
- fainting
- feeling dizzy
- abdominal pain or discomfort
- skin rash and 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 heartbeat
• an increase in the levels of a substance called creatine kinase in your blood which is involved in metabolism which may be seen in blood tests
• increased salivation in the mouth.

**Rare** (may affect up to 1 in 1,000 people):

• extrapyramidal symptoms (EPS) which include involuntary movements, tremors and rigidity, body restlessness, muscle contractions and changes in breathing and heart rate.

**Reporting of side effects**
If you get any of the 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](http://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/bottle 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.
• Donepezil Hydrochloride 5 mg Film-coated Tablet: Each tablet contains 5 mg donepezil hydrochloride. (equivalent to 4.56 mg donepezil).
• Donepezil Hydrochloride 10 mg Film-Coated Tablet: Each tablet contains 10 mg donepezil hydrochloride. (equivalent to 9.12 mg donepezil).

• The other ingredients are:
  Tablet core: lactose monohydrate (see section 2, ‘Donepezil Hydrochloride contains lactose’); maize starch; hydroxypropylcellulose; microcrystalline cellulose and magnesium stearate. Tablet coating: hypromellose; titanium dioxide (E171) and macrogol.

**What Donepezil Hydrochloride looks like and contents of the pack**

Your medicine is in the form of a film-coated tablet.

Donepezil Hydrochloride 5 mg Film-coated Tablets are white, film-coated, round tablets marked with “DL” over “5” on one side and “G” on the reverse.
Donepezil Hydrochloride 10 mg Film-coated Tablets are white, film-coated, round tablets, marked with “DL” over “10” on one side and “G” on the reverse.

Donepezil Hydrochloride 5 mg Film-coated Tablets are available in blisters containing 7, 10, 28, 30, 56, 60, 84, 98, 100 film-coated tablets, calendar packs of 28 and 98 and blister unit dose of 50 x 1.

Donepezil Hydrochloride 5 mg Film-coated Tablets are also available in bottles containing 100 and 250 film-coated tablets.

Donepezil Hydrochloride 10 mg Film-coated Tablets are available in blisters containing 10, 28, 30, 56, 60, 84, 98, 100 Film-Coated Tablets, calendar packs of 28 and 98 and blister unit dose 50 x 1.

Donepezil Hydrochloride 10 mg Film-coated Tablets are also available in bottles containing 100 and 250 film-coated tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

**Manufacturer**

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.
Generics [UK] Ltd, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

This leaflet was last revised in 07/2017