Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

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 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 Alzheimer’s disease. The symptoms include increasing memory loss, confusion and behavior changes, as well as difficulty in carrying out normal daily activities.

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

• You may have further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if they are the same age or older.

• If you are allergic to donepezil hydrochloride, to piperidine derivatives or any of the other ingredients of this medicine (listed in section 6).

3. How to take Donepezil hydrochloride

Tell your doctor or pharmacist if you are taking, have recently taken or might take use any other medicines, including medicines obtained without a prescription. It also applies to medicines you have taken or might take in the future. Your doctor or pharmacist will need to know about any other medicines you are taking.

Other medicines and Donepezil hydrochloride

- Other medicines that may affect acetylcholinesterase activity such as carbamazepine or phenytoin (anti-epileptic medicines) may take sometimes 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:

- Anticoagulants e.g. warfarin
- Anti-inflammatory (NSAID) drugs such as ibuprofen, or diclofenac sodium
- Antidepressants e.g. venlafaxine, citalopram
- Antihistamines e.g. a loratadine or promethazine
- Antidepressants e.g. fluoxetine
- Antidepressants e.g. paroxetine, citalopram, desvenlafaxine
- Medicines obtained without a prescription. It also applies to medicines you have taken or might take in the future. Your doctor or pharmacist will need to know about any other medicines you are taking.

4. Possible side effects

• your ability to drive a machine 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 cramps. If you experience any of these effects you must not drive or operate machinery.

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 medicinal product.

5. How to store Donepezil hydrochloride

- Keep the container of the medicine tight closed.

- Do not change the dose unless told to do so by your doctor.

- Do not take any more medicine than you should. If you take more Donepezil hydrochloride than you should contact your doctor or the nearest hospital emergency department immediately if you take more of the medicine than you should.

- Take any remaining tablets with you.
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.

- Severe reactions e.g. hepatitis. The symptoms of hepatitis are feeling or being tired, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, dark urine (which may affect up to 1 in 1,000 people).
- Stomach or duodenal ulcers. The symptoms of ulcers are stomach pain and discomfort (which may affect up to 1 in 100 people).

- Breathing in the stomach or intestines. This may cause you to pass black tar like stools or blood from the rectum (which may affect up to 1 in 100 people).
- Infections (which 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") (which may affect up to 1 in 10,000 people).
- Black tar like stools or visible blood from the rectum (may affect up to 1 in 10,000 people).
- Loss of consciousness (a disorder called “Neuroleptic Malignant Syndrome”). The symptoms of this disorder can include:
  - Uncontrollable fever
  - Shaking or uncontrollable movement especially of the face and tongue but also of the limbs
  - Difficulty in sleeping (insomnia)
  - 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).

Rare side effects (may affect up to 1 in 10,000 people):
- Stiffness, shaking or uncontrollable movement especially of the face and tongue but also of the limbs
- 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).
- Seizures (fits) or convulsions (may affect up to 1 in 100 people).
- Breathing in the stomach or intestines. This may cause you to pass black tar like stools or blood from the rectum (which may affect up to 1 in 100 people).
- Infections (which 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") (which may affect up to 1 in 10,000 people).
- Black tar like stools or visible blood from the rectum (may affect up to 1 in 10,000 people).
- Loss of consciousness (a disorder called “Neuroleptic Malignant Syndrome”). The symptoms of this disorder can include:
  - Uncontrollable fever
  - Shaking or uncontrollable movement especially of the face and tongue but also of the limbs
  - Difficulty in sleeping (insomnia)
  - 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).