

Package leaflet: Information for the user

Donepezil Hydrochloride 1mg/1ml Oral Solution

You and your caregiver should 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 of the 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 1mg/1ml Oral Solution is and what it is used for
2. What you need to know before you take Donepezil Hydrochloride 1mg/1ml Oral Solution
3. How to take Donepezil Hydrochloride 1mg/1ml Oral Solution
4. Possible side effects
5. How to store Donepezil Hydrochloride 1mg/1ml Oral Solution
6. Contents of the pack and other information

1. What Donepezil Hydrochloride 1mg/1ml Oral Solution 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 to 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 1mg/1ml Oral Solution is for use in adult patients only.

2. What you need to know before you take Donepezil Hydrochloride 1mg/1ml Oral Solution

Do not take Donepezil Hydrochloride 1mg/1ml Oral Solution:

- if you are allergic to (hypersensitive) to donepezil hydrochloride, or to piperidine derivatives, or any of the other ingredients of Donepezil Hydrochloride 1mg/1ml Oral Solution listed in section 6
- if you are breast feeding

Warnings and precautions:

Talk to your doctor or pharmacist before taking Donepezil Hydrochloride 1mg/1ml Oral Solution if you have ever 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
- inherited intolerance of a sugar known as fructose

Also tell your doctor if you are pregnant or think you might be pregnant.

Children

Donepezil Hydrochloride 1mg/1ml Oral Solution is not recommended for use in children.

Other medicines and Donepezil Hydrochloride 1mg/1ml Oral Solution

Tell your doctor or pharmacist if you are taking, or have recently taken, any other medicine. 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 1mg/1ml Oral Solution. This is because these medicines may weaken or strengthen the effects of Donepezil Hydrochloride 1mg/1ml Oral Solution.

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 (propranolol 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 1mg/1ml Oral Solution. This is because Donepezil Hydrochloride 1mg/1ml Oral Solution may affect the amount of anaesthetic needed.

Donepezil Hydrochloride 1mg/1ml Oral Solution 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 1mg/1ml Oral Solution.

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 1mg/1ml Oral Solution with food, drink and alcohol

Food will not influence the effect of Donepezil Hydrochloride 1mg/1ml Oral Solution. Donepezil Hydrochloride 1mg/1ml Oral Solution should not be taken with alcohol because alcohol may change its effect.

Pregnancy, breast-feeding and fertility

Donepezil Hydrochloride 1mg/1ml Oral Solution must not be used while breastfeeding. If you are pregnant, think you might be pregnant or are planning to have a baby, ask your doctor for advice before taking any 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 1mg/1ml Oral Solution.

This medicine contains:

- sorbitol (E420) – if you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product. Sorbitol is a source of fructose. A 5ml dose of Donepezil Hydrochloride 1mg/1ml Oral Solution supplies 1.25g of sorbitol and a 10ml dose of Donepezil Hydrochloride 1mg/1ml Oral Solution supplies 2.5g of sorbitol.
- methyl parahydroxybenzoate (E218) which may cause allergic reactions (possibly delayed).
- sodium metabisulphite (E223) which may rarely cause hypersensitivity reactions and bronchospasm.

3. How to take Donepezil Hydrochloride 1mg/1ml Oral Solution

How much Donepezil Hydrochloride 1mg/1ml Oral Solution should you take?

Usually, you will start by taking 5ml every night. After one month, your doctor may tell you to take 10ml every night. To take a 5ml dose pour the liquid into the dosing spoon to the line of 5ml. To take a 10ml dose pour the liquid into the dosing spoon to the line of 10ml. The amount of Donepezil Hydrochloride 1mg/1ml you will take may change depending on the length of time you have been taking this medicine and on what your doctor recommends.

The maximum recommended dose is 10ml each night. After taking your dose you should wash the dosing spoon with water and leave to air dry.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Do not alter the dose yourself without your doctor's advice.

Route and method of administration

Donepezil Hydrochloride 1mg/1ml Oral Solution should be taken orally in the evening just prior to retiring.

For how long should you take Donepezil Hydrochloride 1mg/1ml Oral Solution?

Your doctor or pharmacist will advise you on how long you should continue to take your medicine. You will need to see your doctor from time to time to review your treatment and assess your symptoms.

If you stop taking Donepezil Hydrochloride 1mg/1ml Oral Solution

Do not stop taking Donepezil Hydrochloride 1mg/1ml Oral Solution unless told to do so by your doctor. If you stop taking Donepezil Hydrochloride 1mg/1ml Oral Solution the benefits of your treatment will gradually fade away.

If you take more Donepezil Hydrochloride 1mg/1ml Oral Solution than you should

DO NOT take more medicine than your doctor has told you to. 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 bottle 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 1mg/1ml Oral Solution

If you forget to take your medicine, just take your normal dose of medicine the following day at the usual time. Do not take a double dose to make up for a forgotten dose. If you forget to take your medicine for more than one week, call your doctor before taking any more.

4. Possible side effects

Like all medicines, Donepezil Hydrochloride 1mg/1ml Oral Solution can cause side effects, although not everybody gets them.

The following side effects have been reported by people taking Donepezil Hydrochloride 1mg/1ml Oral Solution.

Tell your doctor if you have any of these effects while you are taking Donepezil Hydrochloride 1mg/1ml Oral Solution.

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 (probably affecting fewer than 1 in 1000)
- stomach or duodenal ulcers. The symptoms of ulcers are stomach pain and discomfort (indigestion) felt between the navel and the breast bone (probably affecting fewer than in 100)
- bleeding in the stomach or intestines. This may cause you to pass black tar like stools or visible blood from the rectum (probably affecting fewer than 1 in 100)
- seizures (fits) or convulsion (probably affecting fewer than 1 in 100)
- fever with muscle stiffness, sweating or a lowered level of consciousness (a disorder called “Neuroleptic Malignant Syndrome) (probably affecting fewer than 1 in 10,000 people)

Very common side effects (probably affecting more than 1 in 10):

- diarrhoea
- feeling or being sick
- headaches

Common side effects (probably affecting up to 1 in 10)

- muscle cramp
- tiredness
- difficulty in sleeping (insomnia)
- the common cold
- loss of appetite
- hallucinations (seeing or hearing things that are not really there)
- 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 (probably affecting fewer than 1 in 100)

- slow heart beat

Rare side effects (probably affecting fewer than 1 in 1000)

- stiffness, shaking or uncontrollable movement especially of the face and tongue but also of the limbs.

You should tell your doctor if you notice any other side effects not listed in this leaflet while you are taking Donepezil Hydrochloride 1mg/1ml Oral Solution.

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 national reporting system listed below:

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland

IMB Pharmacovigilance,

Earlsfort Terrace, IRL - Dublin 2

Tel: +353 1 6764971 Fax: +353 1 6762517

Website: www.imb.ie

e-mail: imbpharmacovigilance@imb.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Donepezil Hydrochloride 1mg/1ml Oral Solution

- Keep out of the sight and reach of children.
- This medicinal product does not require any special temperature storage conditions.
- Once the bottle is opened, use within 2 months. You may find it helpful to write the date you first opened the bottle in the space provided on the bottle label.
- DO NOT use Donepezil Hydrochloride 1mg/1ml Oral Solution after the expiry date that is printed on the label after EXP. The expiry date refers to the last day of that month.
- If your doctor tells you to stop taking your medicine, you should return any you have not used to your pharmacist.
- 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 1mg/1ml Oral Solution contains?

The active substance is donepezil hydrochloride.

- 5ml of Donepezil Hydrochloride 1mg/1ml Oral Solution contains 5mg of donepezil hydrochloride
- 10ml of Donepezil 1mg/ml Oral Solution contains 10mg of donepezil hydrochloride
- Each 5ml dose contains 1.25g of sorbitol.
- The other ingredients are sorbitol solution (E420), hydroxyethylcellulose, sodium benzoate (E211), sethyl parahydroxybenzoate (E218), propylene glycol (E1520), sodium metabisulfite (E223), strawberry flavour, HCL sol 10%, purified water.

What does Donepezil Hydrochloride 1mg/1ml Oral Solution look like?

Donepezil Hydrochloride 1mg/1ml Oral Solution is a clear colourless liquid with a strawberry odour.

What is in a pack of Donepezil Hydrochloride 1mg/1ml Oral Solution?

Donepezil Hydrochloride 1mg/1ml Oral Solution is available in one strength of 1mg/1ml and is supplied in bottles of 150 ml. The package also includes a 10ml dosing spoon.

Marketing Authorisation Holder

Rosemont Pharmaceutical Ltd
Rosemont House Yorkdale Industrial Park, Braithwaite Street
Leeds, LS11 9XE, UK

Manufacturer:

1. Rafarm SA, Thesi Pousi- Hatzi, Agiou Louka, Peania, Attiki 19002, P.O. Box 37, Greece

or

2. Rosemont Pharmaceuticals Ltd, Rosemont House, Yorkdale Industrial Park, Braithwaite Street, Leeds LS 11 9XE (alternative manufacturer)

For any information about this medicinal product, please contact the Marketing Authorisation Holder, details provided above.

This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom	Donepezil Hydrochloride 1mg/1ml Oral Solution
Ireland	Donepezil Hydrochloride 1mg/1ml Oral Solution
Germany	Donepezilhydrochlorid Rosemont 1mg/ml Lösung zum Einnehmen
Greece	Rafazil 1mg/ml oral solution
Cyprus	Rafazil 1mg/ml oral solution

This leaflet was last revised in April 2014.