
1.3.1 Core Package Leaflet

Package leaflet: Information for the user

Donepezil hydrochloride Synthon 5 mg film-coated tablets
Donepezil hydrochloride Synthon 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 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 hydrochloride belongs to a group of medicines called **acetylcholinesterase inhibitors**.

Donepezil hydrochloride is used to treat the symptoms of dementia in people diagnosed as having mild to moderately severe **Alzheimer's Disease** (senile dementia). It is only used 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**, to related substances (**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. Check if one of the warnings listed below applies to you or applied to you in the past. **Please tell your doctor:**

- if you have or ever had a **heart problem** (specifically the sick sinus syndrome or a comparable condition). Donepezil hydrochloride may slow down your heart rate.
- if you ever had **stomach or duodenal ulcers** or if you use a certain type of **painkiller** (Non-Steroidal Anti-Inflammatory Drugs - **NSAIDs**). Your doctor will monitor your symptoms.
- if you have **difficulty passing urine**. Your doctor will monitor your symptoms.
- if you ever had a **seizure**. Donepezil hydrochloride may cause a new seizure. Your doctor will monitor your symptoms.
- if you have **asthma or other long term lung disease**. Your symptoms could get worse.
- if you have been told by your doctor that you have **an intolerance to some sugars**, such as lactose.

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.

Children and adolescents

Donepezil hydrochloride is not recommended for children and adolescents below the age of 18 years.

Other medicines and Donepezil hydrochloride

Other medicines may be affected by Donepezil hydrochloride. They, in turn, may affect how well Donepezil hydrochloride works. Donepezil hydrochloride can interact with:

- general anaesthetics. If you are going to have an **operation** that requires you to have a **general anaesthetic**, you should tell your doctor and the

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anaesthetist that you are taking Donepezil hydrochloride. This is because your medicine may affect the amount of anaesthetic needed.

- medicines used to control heart rhythm (**quinidine**), antifungal medicines (**ketoconazole and itraconazole**), specific types of antibiotics (**erythromycin**) and medicines used for the treatment of depression (selective serotonin-reuptake inhibitors, SSRIs, such as **fluoxetine**). These medicines can intensify the effect of Donepezil hydrochloride.
- medicines used for the treatment of tuberculosis (**rifampicin**), medicines used to treat epilepsy (**phenytoin and carbamazepine**). These medicines can reduce the effect of Donepezil hydrochloride.
- medicines used as short-term muscle relaxation in anaesthesia and intensive care (**succinylcholine**), other muscle relaxants, medicines that stimulate a certain part of the nervous system (**cholinergic agonists**), and certain blood pressure lowering medicines (**beta blockers**). The effect of both medicines is increased.
- medicines that inhibit a certain part of the nervous system (**cholinergic antagonist**).
- pain killers or treatment for arthritis such as **acetylsalicylic acid**, non-steroidal anti-inflammatory (NSAID) medicines such as **ibuprofen, or diclofenac**.
- other Alzheimer's disease medicines, e.g. **galantamine**.
- medicines obtained without a prescription e.g. **herbal remedies**.

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

Donepezil hydrochloride with food, drink and alcohol

Food will not influence the effect of Donepezil hydrochloride.

Alcohol may change the effect of Donepezil hydrochloride. Therefore, Donepezil hydrochloride should not be taken with alcohol.

Pregnancy, breast-feeding and fertility

Donepezil hydrochloride should **not be used while breastfeeding**.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor 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. Moreover, Donepezil hydrochloride can cause **fatigue, dizziness and muscle cramps** and if affected you **must not drive or operate machinery**.

Donepezil hydrochloride contains lactose

Donepezil hydrochloride contains the mild sugar **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 has told you. Check with your doctor or pharmacist if you are not sure.

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

The tablet strength you take may change depending on the length of time you have been taking the medicine and on what your doctor will recommend.

The **recommended starting dose** is 1 tablet Donepezil hydrochloride 5 mg (5 mg donepezil hydrochloride) / 5 mg donepezil hydrochloride every night. After one month, your doctor may tell you to take 2 tablets Donepezil hydrochloride 5 mg (10 mg donepezil hydrochloride) / 1 tablet Donepezil hydrochloride 10 mg (10 mg donepezil hydrochloride) every night. The maximum recommended dose is 10 mg each night.

For doses not realisable/practicable with this strength, other strengths of this medicinal product are available.

No dosage adjustment is required if you have **kidney problems**.

If you have **mild to moderate liver problems**, your dose needs to be gradually and carefully adjusted to your needs by your doctor. If you have **severe liver problems**, you should not take Donepezil hydrochloride (see section 2, Before you take Donepezil hydrochloride). If you have an unexplained liver disease, your doctor may decide to stop your treatment with Donepezil hydrochloride completely.

Take your Donepezil hydrochloride tablet by mouth with a **drink of water at night** before you go to bed.

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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.

If you take more Donepezil hydrochloride than you should

Do not take more than one tablet each day. If you take more Donepezil hydrochloride than you should, symptoms such as nausea, vomiting, secretion of saliva (salivation), sweating, slow heartbeat (bradycardia), low blood pressure (hypotension), breathing difficulties (respiratory depression), muscle weakness (collapse) and involuntary contractions of the muscles (convulsions) might occur as well as increasing muscles weakness, a possible life threatening condition.

If you have taken more than you should, **contact your doctor immediately**. 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.

If you forget to take Donepezil hydrochloride

Do not take a double dose to make up for a forgotten tablet. Skip the missed dose and take the next tablet at the usual time the following day. If you forget to take your medicine for more than a week, call your doctor before taking any more medicine.

If you stop taking Donepezil hydrochloride

Do not stop taking your tablets, even if you are feeling well, unless your doctor tells you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Donepezil hydrochloride 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

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the skin and eyes, and dark coloured urine (may affect up to 1 in 1,000 people).

- 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).
- fever with muscle stiffness, sweating or a lowered level of consciousness (a disorder known as “Neuroleptic Malignant Syndrome”) (may affect up to 1 in 10,000 people).

Very common side effects (may affect more than 1 in 10 people)

Diarrhoea • nausea • headache

Common side effects (may affect up to 1 in 10 people)

A common cold • loss of appetite (anorexia) • imagining things that are not really there (hallucinations) • agitation • aggressive behaviour • unusual dreams including nightmares • fainting (syncope) • dizziness • inability to sleep (insomnia) • vomiting • abdominal disturbances • rash • itch (pruritus) • muscle cramps • urinary incontinence • fatigue • pain • accident

Uncommon side effects (may affect up to 1 in 100 people)

Slow heartbeat (bradycardia) • minor increase in serum concentration of a certain muscle enzyme (creatine kinase)

Rare side effects (may affect up to 1 in 1,000 people)

Uncontrolled movements of the body or face (extrapyramidal symptoms) • certain disorders in heart conduction leading to heart rhythm disorder (sino-atrial block, atrioventricular block)

Your doctor may decide to reduce your dose or stop your treatment to resolve these side-effects.

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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail:

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medsafety@hpra.ie. 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 blister and carton after 'EXP'. The first two digits indicate the month and the last four digits indicate the year. 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 tablets
Each tablet contains 5.22 mg donepezil hydrochloride monohydrate, equivalent to 5 mg donepezil hydrochloride, equivalent to 4.56 mg of donepezil.
Donepezil hydrochloride 10 mg, film-coated tablets
Each tablet contains 10.44 mg donepezil hydrochloride monohydrate, equivalent to 10 mg donepezil hydrochloride, equivalent to 9.12 mg of donepezil.
- The other ingredients in the tablet core are lactose monohydrate, microcrystalline cellulose (E460), sodium starch glycolate (type A), hydroxypropyl cellulose (E463), magnesium stearate (E572).
The ingredients in the tablet coating are hypromellose (E464), iron oxide yellow (E172) (only for Donepezil hydrochloride 10 mg, film-coated tablets), lactose monohydrate, macrogol 4000 and titanium dioxide (E171).

What Donepezil hydrochloride looks like and contents of the pack

Donepezil hydrochloride 5 mg, film-coated tablets

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Donepezil hydrochloride 5 mg, film-coated tablets are white, round and biconvex film-coated tablets, debossed with D9EI on one side and 5 on the other side.

Donepezil hydrochloride 10 mg, film-coated tablets

Donepezil hydrochloride 10 mg, film-coated tablets are yellow, round and biconvex film-coated tablets, debossed with D9EI on one side and 10 on the other side.

The film-coated tablets are available in blisters of 7, 28, 30, 50, 56, 60, 84, 98, 100, 120 film-coated tablets and in unit dose blisters of 50 film-coated tablets (for hospital use only).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Synthon BV
Microweg 22
6545 CM Nijmegen
The Netherlands

Manufacturers:

Synthon BV
Microweg 22
6545 CM, Nijmegen
The Netherlands

Synthon Hispania S.L.
Castelló 1, Polígono Las Salinas
08830 San Boi de Lloregat
Spain

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

Czech Republic	Alzil 5 mg, potahovaná tablet Alzil 10 mg, potahovaná tableta
Germany	Donepezilhydrochlorid Synthon 5 mg, Filmtabletten Donepezilhydrochlorid Synthon 10 mg Filmtabletten
Greece	Donepezil Synthon 5 mg, Επικαλυμμένο με λεπτό υμένιο δισκίο

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	Donepezil Synthon 10 mg, Επικαλυμμένο με λεπτό υμένιο δισκίο
France	Donepezil Synthon 5 mg, Comprimé pelliculé Donepezil Synthon 10 mg, Comprimé pelliculé
Ireland	Donepezil Synthon 5 mg, film-coated tablets Donepezil Synthon 10 mg, film-coated tablets
Iceland	Donepezil Medical 5 mg, filmuhúðuð tafla Donepezil Medical 10 mg, filmuhúðuð tafla
Norway	Donepezil Synthon 5 mg, tablett, filmdrasjert Donepezil Synthon 10 mg, tablett, filmdrasjert
Poland	Cognezil, 5 mg, tabletki powlekane Cognezil, 10 mg, tabletki powlekane
Romania	Cognezil 5 mg, Comprimat filmat Cognezil 10 mg, Comprimat filmat
Slovak Republic	Cognezil 5 mg, filmom obalená tablet Cognezil 10 mg, filmom obalená tablet

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