

Package leaflet: Information for the user

Donesyn 5 mg Film-coated Tablets Donesyn 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 Donesyn is and what it is used for
2. What you need to know before you take Donesyn
3. How to take Donesyn
4. Possible side effects
5. How to store Donesyn
6. Contents of the pack and other information

1. What Donesyn is and what it is used for

Donesyn contains the active substance donepezil hydrochloride. It belongs to a group of medicines called **acetylcholinesterase inhibitors**.

Donesyn 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 Donesyn

Do not take Donesyn

- if you are **allergic to donepezil hydrochloride, or 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 Donesyn.

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 such as **irregular or very slow heart beat, heart failure, myocardial infarction**). Donesyn may slow down your heart rate.
- if you have or have had a **heart condition** called '**prolonged QT interval**' or a history of certain abnormal heart rhythms called **Torsade de Pointes** or if anyone in your family have 'prolonged QT interval'.
- if you have or have had **low levels of magnesium or potassium** in your blood.
- 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**. Donesyn 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.

Donesyn 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 Donesyn.

Children and adolescents

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

Other medicines and Donesyn

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

Other medicines may be affected by Donesyn. They, in turn, may affect how well Donesyn works.

Donesyn 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 anaesthetist that you are taking Donesyn. This is because your medicine may affect the amount of anaesthetic needed.
- medicines used to control heart rhythm (**quinidine**), antifungal medicines (**ketconazole 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 Donesyn.
- medicines used for the treatment of tuberculosis (**rifampicin**), medicines used to treat epilepsy (**phenytoin and carbamazepine**). These medicines can reduce the effect of Donesyn.
- 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**.
- medicines for heart rhythm problems (e.g. **amiodarone, sotalol, and quinidine**)
- depression (e.g. **citalopram, escitalopram, amitriptyline**), medicines for psychoses (e.g. **pimozide, sertindole, ziprasidone**), medicines for bacterial infections (such as **clarithromycin, erythromycin, levofloxacin, moxifloxacin**).

Donesyn with food, drink and alcohol

Food will not influence the effect of Donesyn.

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

Pregnancy, breast-feeding and fertility

Donesyn 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, Donesyn can cause **fatigue, dizziness and muscle cramps** and if affected you **must not drive or operate machinery**.

Donesyn contains lactose and sodium

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

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Donesyn

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 Donesyn 5 mg (5 mg donepezil hydrochloride) / **5 mg donepezil hydrochloride** every night. After one month, your doctor may tell you to take 2 tablets Donesyn 5 mg (10 mg donepezil hydrochloride) / 1 tablet Donesyn 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 Donesyn (see section 2, Before you take Donesyn). If you have an unexplained liver disease, your doctor may decide to stop your treatment with Donesyn completely.

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

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 Donesyn than you should

Do not take more than one tablet each day. If you take more Donesyn 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 muscle 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 Donesyn

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 Donesyn

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, 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 (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).
- 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).

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 • accidents (patients may be more prone to falls and accidental injury)

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)

Not known side effects (frequency cannot be estimated from the available data)

Changes in the heart activity which can be seen on an electro-cardiogram (ECG) called ‘prolonged QT interval’ • fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as Torsade de Pointes

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 the national reporting system:

HPRA Pharmacovigilance

Website: www.hpra.ie

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

5. How to store Donesyn

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 Donesyn contains

- The active substance is donepezil hydrochloride.

Donesyn 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.

Donesyn 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 (E470b). The ingredients in the tablet coating are hypromellose (E464), iron oxide yellow (E172) (only for Donesyn 10 mg film-coated tablets), lactose monohydrate, macrogol 4000 and titanium dioxide (E171).

What Donesyn looks like and contents of the pack

Donesyn 5 mg film-coated tablets

Donesyn 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.

Donesyn 10 mg film-coated tablets

Donesyn 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:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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:

Germany	Donesyn 5/10 mg Filmtabletten
Bulgaria	Donesyn 5/10 mg Филмирана таблетка
Czech Republic	Donpethon 5/10 mg, potahovaná tableta
Estonia	Donesyn 5/10 mg
Greece	Donepezil Synthon Hispania 5/10 mg

Finland	Donesyn 5/10 mg tabletti
Hungary	Donesyn 5/10 mg filmtabletta
Ireland	Donesyn 5/10 mg film-coated tablets
Iceland	Donesyn 5/10 mg filmuhúðaðar töflur
Lithuania	Donesyn 5/10 mg plėvele dengtos tabletės
Latvia	Donesyn 5/10 mg apvalkotās tabletes
Norway	Donesyn 5/10 mg tablett
Poland	Donesyn
Portugal	Dosylien 5/10 mg comprimidos revestidos por película
Romania	Donesyn 5/10 mg
Slovenia	Donesyn 5/10 mg filmsko obložene tablete
Slovakia	Donesyn 5/10 mg

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