

PACKAGE LEAFLET: INFORMATION FOR THE USER

Donesyn 5mg Orodispersible Tablets Donesyn 10mg Orodispersible Tablets

Donepezil Hydrochloride

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Donesyn is and what it is used for
2. Before you take Donesyn
3. How to take Donesyn
4. Possible side effects
5. How to store Donesyn
6. Further information

1. WHAT DONESYN IS AND WHAT IT IS USED FOR

Donesyn (donepezil hydrochloride) 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. It is for use only in adult patients.

2. BEFORE YOU TAKE DONESYN

Do not take Donesyn if:

- you are allergic (hypersensitive) to donepezil hydrochloride, or to piperidine derivatives, or any other ingredients of Donesyn listed in section 6.

Take special care with Donesyn

Tell your doctor or pharmacist if:

- you have ever had stomach or duodenal ulcers
- you have ever had a seizure (fit) or convulsion
- you have a heart condition (irregular or very slow heart beat)
- you have asthma (dyspnoea) or other long term lung disease
- you have ever had any liver problems or hepatitis (inflammation of the liver)
- you have difficulty passing urine or mild kidney disease

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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Always tell your doctor or pharmacist if you are using or receiving any of the following medicines in addition to Donesyn:

- 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 medicines e.g. ketoconazole
- muscle relaxants e.g. diazepam, succinylcholine
- anti-depressants e.g. fluoxetine
- anticonvulsants (medicines used in prevention of the occurrence of several types of seizures) e.g. phenytoin, carbamazepine
- medication for a heart condition e.g. quinidine, beta-blockers (propranolol and atenolol)
- 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 (narcosis) 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.

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

Taking Donesyn with food and drink

Food does not have any effect on this medication. **Donesyn should not be taken with alcohol**, as alcohol may reduce the levels of donepezil.

Pregnancy and breast-feeding

You should not use donepezil hydrochloride if you are pregnant or are breast feeding.

Ask your doctor or your pharmacist for advice before taking any medicine.

Driving and using machines

Do not drive because 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.

Do not use any tools or machines because your medicine can cause fatigue, dizziness and muscle cramp and if affected you must not drive or operate machinery.

Important information about some of the ingredients of Donesyn

Contains source of phenylalanine. May be harmful for people with phenylketonuria.

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

3. HOW TO TAKE DONESYN

Always take Donesyn exactly as your doctor has told you. You should check with your doctor or your pharmacist if you are not sure.

The usual dose is 5 mg every night. After one month, your doctor may tell you to take 10 mg every night. The maximum recommended dose is 10 mg each night.

Take your Donesyn tablet by mouth at night before you go to bed. The tablet should be placed on the tongue and allowed to dissolve before swallowing with or without water according to your preference. The tablet strength you will take may change depending on the length of time you have been taking the medicine and on what your doctor will recommend. You should always follow your doctor's, or pharmacist's advice about how and when to take your medicine. Do not alter the dose yourself without your doctor's advice. Your doctor or pharmacist will advise you on how long you should continue to take your tablets. You will need to see your doctor from time to time 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 do, you may experience nausea, vomiting, drooling, sweating, slow heart rate, low blood pressure (light-headedness or dizziness when standing), difficulty in breathing, collapse and convulsion. Call your doctor immediately or contact the local hospital. 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

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

If you stop taking Donesyn

Do not stop taking the tablets unless told to do so by your doctor. If you have any further question on the use of this product, ask your doctor or your pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Donesyn can have side effects, although not everybody gets them. In most cases these go away without having to stop treatment. Tell your doctor if you have any of these effects and if they are too uncomfortable for you.

Patients taking Donesyn have reported the following side effects:

Tell your doctor if you have any of these effects while you are taking Donesyn

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 1,000)
- 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 1 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 convulsions (probably affecting fewer than 1 in 100)
- fever with muscle stiffness, sweating or a lowered level of consciousness (a disorder called “Neuroleptic Malignant Syndrome”).

Very common side effects (*affects more than 1 user in 10*)

- diarrhoea
- feeling or being sick
- headaches

Common side effects (*affects 1 to 10 users in 100*)

- common cold
- loss of appetite
- hallucinations (seeing or hearing things that are not really there)
- agitation
- aggressive behaviour
- fainting
- dizziness
- insomnia (difficulty in sleeping)
- accidents
- abdominal disturbances
- rash
- itching
- muscle cramp
- urinary incontinence
- fatigue
- pain

Uncommon side effects (*affects 1 to 10 users in 1,000*)

- slow heart beat

Rare side effects (*affects 1 to 10 users in 10,000*)

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DONESYN

Keep out of the reach and sight of children.

Do not use Donesyn orodispersible tablets after the expiry date which is stated on the blister and the carton. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions.

Store in the original blister in order to protect from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Donesyn contain

The active substance in Donesyn is donepezil hydrochloride.

Each tablet contains 5 mg of donepezil hydrochloride.

Each tablet contains 10 mg of donepezil hydrochloride.

The other ingredients are:

Polacrillin potassium, cellulose, microcrystalline, lactose monohydrate (spray dried), monosodium citrate anhydrous, aspartame (E951), croscarmellose sodium, silica colloidal anhydrous, magnesium stearate.

What Donesyn looks like and contents of the pack

Donesyn 5 mg: White to off-white, round, flat tablets with bevelled edges, embossed with '5' on one side and plain on the other.

Donesyn 10 mg: White to off-white, round, flat tablets with bevelled edges, embossed with '10' on one side and plain on the other.

Packs:

Blisters of 7, 10, 14 tablets

Pack sizes:

10, 14, 28, 30, 56, 98, 126, 154 and 196 orodispersible tablets

10, 14, 28, 30, 56, 98, 126, 154 and 196 orodispersible tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder:

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

Manufacturer:

Genepharma S.A, 18th Km Marathonos Avenue, 153 51 Pallini Attikis, Greece
STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

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

This medicinal product is authorised in the member states of the EEA under the following names:

AT: Donepezil STADA 5 mg and 10 mg Schmelztabletten
BE: Donepezil Instant EG 5 mg and 10 mg orodispergeerbare tabletten
LU: Donepezil Instant EG 5 mg and 10 mg comprimés orodispersibles
CZ: Adonep ORO TAB 5 mg and 10 mg
DE: Donepezilhydrochlorid AL 5 mg and 10 mg Schmelztabletten
ES: Donepezilo Flas STADA 5 mg and 10 mg comprimidos bucodispersables EFG
IE: Donesyn 5 mg and 10 mg orodispersible tablets
PL: Donepezil STADA ORO
PT: Donepezilo Ciclum
RO: Donepezil STADA Hemofarm 5 mg and 10 mg comprimate orodispersabile
UK: Donepezil hydrochloride 5 mg and 10 mg orodispersible tablets

This leaflet was last approved in July 2014.