

Package leaflet: Information for the user

Donepezil SymPhar 5 mg film-coated tablets
Donepezil SymPhar 10 mg film-coated tablets

(Donepezil Hydrochloride)

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 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 SymPhar is and what it is used for
2. What you need to know before you take Donepezil SymPhar
3. How to take Donepezil SymPhar
4. Possible side effects
5. How to store Donepezil SymPhar
6. Contents of the pack and other information

1. What Donepezil SymPhar is and what it is used for

Donepezil SymPhar (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 break down of acetylcholine. It is used to treat the symptoms of dementia in people diagnosed as having mild and 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 SymPhar is for use in adult patients only.

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

Do NOT take Donepezil SymPhar

- if you are allergic to donepezil hydrochloride, or to 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 Donepezil SymPhar. Tell your doctor or pharmacist before starting to take Donepezil SymPhar if you have or have 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

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

Other medicines and Donepezil SymPhar

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. 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 SymPhar. This is because these medicines may weaken or strengthen the effects of Donepezil SymPhar.

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 SymPhar. This is because your medicine may affect the amount of anaesthetic needed.

Donepezil SymPhar 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 SymPhar.

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

Donepezil SymPhar with food, drink and alcohol

Food will not influence the effect of Donepezil SymPhar.

Donepezil SymPhar should not be taken with alcohol because alcohol may change its effect.

Pregnancy and breast-feeding

Donepezil SymPhar should not be used while breastfeeding.

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist 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.

Also, your medicine can cause tiredness, dizziness and muscle cramp. If you experience any of these effects you must not drive or operate machinery.

Donepezil SymPhar contains lactose

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

3. How to take Donepezil SymPhar

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much Donepezil SymPhar should you take?

Usually, you will start by taking 5 mg (one white tablet) every night. After one month, your doctor may tell you to take 10 mg (one yellow tablet) every night.

Swallow your Donepezil SymPhar tablet with a drink of water before you go to bed at night.

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 recommends. The maximum recommended dose is 10 mg each night.

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.

For how long should you take Donepezil SymPhar

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 stop taking Donepezil SymPhar

Do not stop taking the tablets unless told to do so by your doctor. If you stop taking Donepezil SymPhar, the benefits of your treatment will gradually fade away.

If you take more Donepezil SymPhar than you should

DO NOT take more than one tablet each day. 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 tablets 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 SymPhar

If you forget to take a tablet, just take one tablet the following day at the usual time. Do not take a double dose to make up for a forgotten tablet.

If you forget to take your medicine for more than one week, call your doctor before taking any more medicine.

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. The following side effects have been reported by people taking Donepezil. **Tell your doctor if you have any of these effects while you are taking Donepezil SymPhar.**

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 (affects 1 to 10 users in 10,000).
- stomach or duodenal ulcers. The symptoms of ulcers are stomach pain and discomfort (indigestion) felt between the navel and the breast bone (affects 1 to 10 users in 1,000).
- bleeding in the stomach or intestines. This may cause you to pass black tar like stools or visible blood from the rectum (affects 1 to 10 users in 1,000).
- seizures (fits) or convulsions (affects 1 to 10 users in 1,000).
- fever with muscle stiffness, sweating or a lowered level of consciousness (a disorder known as “Neuroleptic Malignant Syndrome”) (affects less than 1 user in 10,000).
- Muscle weakness, tenderness or pain and particularly, if at the same time, you fell 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).

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):

- muscle cramp
- tiredness
- difficulty in sleeping (insomnia)
- the common cold
- loss of appetite
- hallucinations (seeing or hearing things that are not really there)
- unusual dreams including nightmares
- 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 (affects 1 to 10 users in 1,000):

- slow heart beat.

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

- stiffness, shaking 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 the national reporting system listed in [Appendix V](#)*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Donepezil SymPhar

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Do not store this medicine above 30°C.

Keep this medicine out of the sight and reach of children.

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 SymPhar contains

- The active substance is donepezil hydrochloride. The 5 mg tablet contains 5 mg of donepezil hydrochloride and the 10 mg tablet contains 10 mg of donepezil hydrochloride.
- The other ingredients are lactose monohydrate, pregelatinized starch, microcrystalline cellulose, colloidal silicon dioxide, magnesium stearate, talc, propylene glycol, hypromellose and titanium dioxide (E171). Additionally, the 10 mg tablet contain yellow iron oxide (E172).

What Donepezil SymPhar looks like and contents of the pack

- 5 mg white to off-white, round, biconvex tablets, embossed with “ML89” on one side and plain on the other side.
- 10 mg yellow, round, biconvex tablets, embossed with “ML 88” on one side and plain on other side.

The tablets are supplied in packs of 28, 56, 84 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

SymPhar Sp. z o.o.
ul. Włoska 1
00-777 Warszawa

Manufacturer

SymPhar Sp. z o.o.
ul. Chełmżyńska 249
04-458 Warszawa

Mawdsley-Brooks and Company Limited
Unit 22, Quest Park, Wheatley Hall Road, Doncaster DN2 4LT
United Kingdom

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

Portugal: Donepezilo SymPhar

Poland: Donepezil SymPhar

This leaflet was last revised in