

PATIENT INFORMATION LEAFLET
DONEPEZIL/GENEPHARM 5 mg & 10 mg Orodispersible tablet
(Donepezil Hydrochloride)

You and your caregiver should read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT DONEPEZIL/GENEPHARM IS AND WHAT IT IS USED FOR

Donepezil/Genepharm (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 breakdown 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/Genepharm is for use in adult patients only.

2. BEFORE YOU TAKE DONEPEZIL/GENEPHARM

Do NOT take Donepezil/Genepharm

- if you are allergic (hypersensitive) to donepezil hydrochloride, or to piperidine derivatives, or any of the other ingredients of Donepezil/Genepharm listed in section 6.

Take special care with Donepezil/Genepharm

Tell your doctor or pharmacist before starting to take Donepezil/Genepharm 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.

Taking other medicines

Please 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/Genepharm. This is because these medicines may weaken or strengthen the effects of Donepezil/Genepharm.

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

Donepezil/Genepharm 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/Genepharm.

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

Taking Donepezil/Genepharm with food and drink

Food will not influence the effect of Donepezil/Genepharm.

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

Pregnancy and breast-feeding

Donepezil/Genepharm should not be used while breastfeeding.

If you are pregnant, or think you might be pregnant, 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.

3. HOW TO TAKE DONEPEZIL/GENEPHARM

How much Donepezil/Genepharm should you take?

Usually, you will start by taking 5 mg every night before you go to bed. After one month, your doctor may tell you to take 10 mg every night before you go to bed. The tablet should be placed on your tongue and allowed to disintegrate 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 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/Genepharm?

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/Genepharm

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

If you take more Donepezil/Genepharm 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/Genepharm

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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Donepezil/Genepharm can cause side effects, although not everybody gets them.

The following side effects have been reported by people taking Donepezil/Genepharm.

Tell your doctor if you have any of these effects while you are taking Donepezil/Genepharm.

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 called "Neuroleptic Malignant Syndrome") (affects less than 1 user in 10,000).

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

5. HOW TO STORE DONEPEZIL/GENEPHARM

DO NOT use Donepezil/Genepharm orodispersible tablets after the expiry date that is printed on the label. The expiry date refers to the last day of that month.

This medicinal product should be stored in temperature below 30°C. As all medicines, keep out of the reach and sight of children.

If your doctor tells you to stop taking your medicine, you should return any you have not used to your pharmacist.

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 do Donepezil/Genepharm orodispersible tablets contain?

The active substance is donepezil hydrochloride.

Donepezil/Genepharm orodispersible tablets are available in two presentations:

- Tablets of 5mg, which contains 5 mg of donepezil hydrochloride.
- Tablets of 10mg, which contains 10 mg of donepezil hydrochloride.

The other ingredients are:

- Polacrillin Potassium, Microcrystalline cellulose, Lactose monohydrate (Spray Dried), Monosodium citrate anhydrous, Aspartame (E951), Croscarmellose sodium, Silica colloidal anhydrous, Magnesium Stearate, Hydrochloric acid for pH adjustments and purified water.

What do Donepezil/Genepharm orodispersible tablets look like?

- **5mg:** White to off-white round, flat tablets, with bevelled edges, embossed with '5' on one side and plain on the other
- **10mg:** White to off-white round, flat tablets, with bevelled edges, embossed with '10' on one side and plain on the other

What is in a pack of Donepezil/Genepharm?

The orodispersible tablets are supplied in packs of 7, 28, 30, 50, 56, 60, 98 or 120 orodispersible tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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