

DONEPEZIL/GENEPHARM ORODISPERSIBLE TABLET

Donepezil Hydrochloride (5mg & 10mg)

What is in this leaflet

1. What Donepezil/Genepharm is used for
2. How Donepezil/Genepharm works
3. Before you use Donepezil/Genepharm
4. How to use Donepezil/Genepharm
5. While you are using it
6. Side effects
7. Storage and Disposal of Donepezil/Genepharm
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Donepezil/Genepharm is used for

Donepezil/Genepharm (donepezil hydrochloride) belongs to a group of medicines called acetylcholinesterase inhibitors.

It is used to treat dementia in people diagnosed as having mild, moderate and severe Alzheimer's disease. The symptoms include increasing memory loss, confusion and behavioral 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.

How Donepezil/Genepharm works

Donepezil increases the levels of a substance (acetylcholine) in the brain involved in memory function by slowing down the breakdown of acetylcholine.

Before you use Donepezil/Genepharm

Tell the doctor about all your present or past health problems. Including:

- Any heart problems including problems with irregular, slow or fast heartbeats.
- 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'.

- Low levels of magnesium or potassium in your blood.

- When you must not use it

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

- Before you start to use it

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

Children and adolescents

Donepezil/Genepharm is not recommended for use in children and adolescents (younger than 18 years of age).

Pregnancy and breast-feeding

Do not take Donepezil/Genepharm if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Donepezil/Genepharm if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Be particularly sure to tell the doctor if you are taking any of the following types of medicines:

- Medicines for heart rhythm problems e.g. amiodarone, sotalol and quinidine.
- Medicines for depression e.g. citalopram, escitalopram, amitriptyline.
- Medicines for psychosis e.g. pimozide, sertindole, ziprasidone.
- Medicines for bacterial infections e.g. clarithromycin, erythromycin, levofloxacin, moxifloxacin.
- Pain killers e.g. nonsteroidal anti-inflammatory drugs (NSAIDs).
- Antifungal e.g. ketoconazole, itraconazole
- Anticonvulsants e.g. phenytoin, carbamazepine
- Muscle relaxant e.g. succinylcholine

How to use Donepezil/Genepharm

- How much to use

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

Initially, the recommended dose is 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 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.

Children and adolescents

Donepezil/Genepharm is not recommended for use in children and

adolescents (younger than 18 years of age).

-When to use it

The tablet should be placed on your tongue and allowed to disintegrate before swallowing, with or without water, according to your preference.

-How long to use it

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 forget to use it

If you forget to take your medicine, take the next dose 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 use too much (overdose)

Contact your doctor or the nearest hospital emergency department immediately if you take more of the medicine than you should. Take this leaflet and any remaining tablets with you.

Overdose symptoms may 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.

While you are using it

-Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Donepezil/Genepharm.

Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

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

-Things to be careful of

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.

This medicine may cause tiredness, dizziness and muscle cramp. If you experience any of these effects, you must not drive or operate machinery and contact your doctor immediately.

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

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.
- stomach or duodenal ulcers. The symptoms of ulcers are stomach pain and discomfort (indigestion) felt between the navel and the breast bone
- bleeding in the stomach or intestines. This may cause you to pass black tar like stools or visible blood from the rectum
- seizures (fits) or convulsions
- fever with muscle stiffness, sweating or a lowered level of consciousness (a disorder called "Neuroleptic Malignant Syndrome")
- 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)

Very common:

- diarrhoea
- feeling or being sick
- headaches

Common:

- 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 behavior
- fainting
- dizziness
- stomach feeling uncomfortable
- rash
- itching
- passing urine uncontrollably
- pain
- accidents (patients may be more prone to falls and accidental injury)

Uncommon:

- slow heart beat
- salivary hypersecretion

Rare:

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

Unknown (frequency cannot be estimated):

- Fast, irregular heart beat and fainting, which could be symptoms of a life-threatening condition known as Torsade de Pointes.
- Changes in the heart activity which can be seen on an electrocardiogram (ECG) called 'prolonged QT interval'.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by or visiting the

website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Manufacturer

GENEPHARM S.A
18th Km Marathonos Avenue, Pallini,
15351, Greece.

**Storage and Disposal of
Donepezil/Genepharm**

- Storage

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

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.

Product Registration Holder

Medispec (M) Sdn Bhd
B-1-07, Jalan SS 25/22,
Taman Mayang,
47301 Petaling Jaya, Selangor, Malaysia

Date of Revision

18/01/2024

NPRA

NPRA (R2) 20/143

This medicinal product should be stored in temperature below 30°C.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

Product Description

- What it looks 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.

- Ingredients

- Active ingredient
Donepezil hydrochloride

- Inactive ingredients
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.

- MAL number(s):

DONEPEZIL/GENEPHARM 5 mg
orodispersible tablet: MAL21116020AZ

DONEPEZIL/GENEPHARM 10mg
orodispersible tablet: MAL21116021AZ