PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Donepezil Teva 5 mg
Film-coated Tablets

Each film-coated tablet contains:
Donepezil hydrochloride (as monohydrate) 5 mg

Donepezil Teva 10 mg
Film-coated Tablets

Each film-coated tablet contains:
Donepezil hydrochloride (as monohydrate) 10 mg

For information about inactive ingredients see section 2 - "Important information about some of the ingredients of the medicine" and section 6 - "Further Information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. Keep this leaflet; you may want to read it again.
This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

For treatment of mild to moderate dementia of Alzheimer's disease.

Therapeutic group:
Acetylcholinesterase inhibitors.
Acetylcholine is involved in the memory processes in the brain. Donepezil increases the amount of acetylcholine by inhibiting its breakdown by acetylcholinesterase.
Donepezil is used to treat symptoms of Alzheimer's disease such as increasing memory loss, confusion and behavioral changes, which affect the normal life routine of the patients.

The medicine is intended for adults only.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:
you are sensitive (allergic) to the active ingredient donepezil hydrochloride, piperidine derivatives or to any of the additional ingredients contained in the medicine (see section 6 - "Further Information").

Special warnings regarding use of the medicine
Before treatment with the medicine, tell the doctor if you suffer or have ever suffered from:
- stomach or duodenal ulcers.
- fits or convulsions.
- heart disease (irregular or very slow heart rate, heart failure or myocardial infarction).
- a heart condition called "prolonged QT interval" or history of a heart rhythm problem called torsade de pointes or if there is a family history of "prolonged QT interval".
- low levels of magnesium or potassium in the blood.
- asthma or other chronic lung disease.
- liver problems or hepatitis.
- difficulty passing urine or mild kidney disease.

Also, tell the doctor if you are pregnant or think that you are pregnant.

Patients with kidney disease can use Donepezil Teva, but the doctor should be consulted.
Patients with mild to moderate liver disease can use Donepezil Teva, but the doctor should be consulted.
The use of the medicine is not recommended in patients with severe liver disease.

Children and adolescents
This medicine is not intended for children and adolescents under 18 years of age.

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, including herbal medicines, tell the doctor or pharmacist, since these medicines may affect the efficacy of Donepezil Teva. In particular, if you are taking:
- medicines for heart rhythm disturbances, e.g., amiodarone, sotalol.
- antidepressants,e.g., citalopram, escitalopram, amitriptyline, fluoxetine.
- medicines for mental disturbances, e.g., pimozide, sertindole, ziprasidone.
- antibiotics,e.g., clarithromycin, erythromycin, levofloxacin, moxifloxacin, rifampicin.
- antifungals, e.g., ketoconazole.
- other medicines to treat Alzheimer's disease, e.g., galantamine.
- painkillers or medicines to treat arthritis, e.g., aspirin, non-steroidal anti-inflammatory drugs (NSAIDs), e.g., ibuprofen or diclofenac sodium.
- anticholinergic medicines, e.g., tolterodine.
- anticonvulsants (for epilepsy), e.g., phenytoin or carbamazepine.
- medicines to treat heart diseases, e.g., quinidine or beta-blockers (e.g., propranolol and atenolol).
- muscle relaxants, e.g., diazepam, succinylcholine.
- general anesthetics.
- Non-prescription medicines, including herbal remedies.

If you are due to undergo an operation that involves general anesthesia, inform the anesthesiologist and the attending doctor that you are taking Donepezil Teva. Donepezil Teva may affect the amount of anesthetic required.
Tell the doctor or pharmacist who your caregiver is. Your caregiver can help you take the medicines as required.

Use of the medicine and food
Food does not influence the effect of the medicine.

Use of the medicine and alcohol consumption
Do not drink alcohol during the course of treatment with Donepezil Teva. Alcohol may affect the action of the medicine.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you are pregnant or are planning to become pregnant, consult the doctor before using Donepezil Teva.
Do not use Donepezil Teva while breast-feeding.

Driving and using machines
Do not drive or operate dangerous machinery when using this medicine, as Alzheimer's disease may affect your ability to drive or operate machinery or dangerous devices. For your safety, you must not perform these activities unless the doctor has allowed you to. Additionally, Donepezil Teva may cause tiredness, dizziness and muscle cramps. If these effects occur, do not drive or operate machinery or dangerous devices.

Important information about some of the ingredients of the medicine
The medicine contains lactose. If you have been told by your doctor that you have an intolerance to certain sugars, consult the doctor before starting treatment with Donepezil Teva.
This medicine contains less than 23 mg sodium per tablet and is therefore considered sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine. The dosage and treatment regimen will be determined by the doctor only.
The usual dosage is generally:
The recommended starting dosage is 5 mg Donepezil Teva every night before bedtime. After one month, the doctor may recommend that you take 10 mg Donepezil Teva every night before bedtime.
The tablet strength may change depending on the length of time you are taking the medicine and on the doctor's recommendations.
The maximum recommended dosage is 10 mg Donepezil Teva each night.
Do not exceed the recommended dose. Do not change the dosage without being instructed to do so by the doctor.

Duration of Donepezil Teva treatment
The doctor or pharmacist will advise you regarding the duration of treatment with Donepezil Teva. Refer to the doctor from time to time to evaluate the treatment and assess your symptoms.

Method of administration
Take the Donepezil Teva tablet whole with a little water before bedtime.
In cases of sleep disturbances, including strange dreams, nightmares or insomnia (see section 4 – "Side effects"), consider taking the medicine in the morning.
The tablet cannot be halved as there is no score line. There is no information regarding crushing or pulverizing the tablet.

If you accidentally took a higher dosage of the medicine or if a child or someone else has accidentally swallowed the medicine, refer immediately to the doctor or proceed to a hospital emergency room and bring the package of the medicine, the leaflet and the remaining tablets with you. Signs of Donepezil Teva overdose may include nausea and vomiting, drooling, sweating, slow heart rate, low blood pressure (dizziness upon standing up), breathing problems, loss of consciousness, fits or convulsions.

If you forgot to take the medicine
If you forgot to take Donepezil Teva at the required time, do not take a double dose to compensate for a forgotten dose. Take the next dose at the regular time and consult the doctor. If you forgot to take Donepezil Teva for more than one week, consult the doctor before you resume taking it. Always adhere to the Donepezil Teva treatment regimen as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting with the doctor.

If you stop taking Donepezil Teva
Do not stop treatment with the medicine unless instructed to do so by the doctor. If you stop taking Donepezil Teva, the benefits of the treatment will gradually disappear. Before stopping, discuss the consequences with the doctor or pharmacist.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Donepezil Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Serious side effects
Refer to the doctor immediately if the following severe side effects occur; you may need urgent medical treatment:
- Liver damage, e.g., hepatitis. The symptoms of hepatitis are: nausea and vomiting, loss of appetite, a general unwell feeling, fever, itching, yellowing of the skin and eyes, and dark-colored urine (occurs at a frequency of up to 1 user in 1,000).
- Stomach or duodenal ulcers. The symptoms are: stomach pain and discomfort (a feeling of indigestion) in the abdominal area between the navel and the breastbone (occurs at a frequency of up to 1 user in 100).
- Bleeding in the stomach or intestines. Manifested as black stool or visible blood in the rectum (occurs at a frequency of up to 1 user in 100).
- Fits or convulsions (occur at a frequency of up to 1 user in 100).
- High fever with muscle stiffness, sweating or lowered level of consciousness [a disturbance called neuroleptic malignant syndrome (NMS)] (occurs at a frequency of up to 1 user in 10,000).
- Muscle weakness, muscle tenderness or pain, and especially if, at the same time, you feel sick, have a fever or dark urine. These signs may be caused by abnormal muscle tissue breakdown, which may be life-threatening and cause kidney problems (this condition is called rhabdomyolysis) (occurs at a frequency of up to 1 user in 10,000).
- Rapid and irregular pulse and fainting, which can be symptoms of a life-threatening condition known as torsade de pointes (the frequency cannot be estimated from the available clinical data).

Additional side effects

Very common side effects (occur at a frequency of more than 1 user in 10):
Diarrhea, headaches.

Common side effects (occur at a frequency of up to 1 user in 10):
Muscle cramps, tiredness, insomnia, common cold, hallucinations (seeing and hearing things that do not really exist), strange dreams including nightmares, restlessness, aggressive behavior, fainting, dizziness, abdominal discomfort, rash, urinary incontinence, pain, accidents (patients are more prone to falling and getting injured).

Uncommon side effects (occur at a frequency of up to 1 user in 100):
Slow heart rate, increased salivation.

Rare side effects (occur at a frequency of up to 1 user in 1,000):
Stiffness, shaking or involuntary movements, especially of the face and tongue but also of the limbs.

Side effects of unknown frequency (the frequency cannot be estimated from the available data):
- Changes in heart activity which can be seen in an electro-cardiogram (ECG), called "prolonged QT interval".
- Increase libido, hypersexuality.
- Pisa syndrome (characterized by involuntary muscle contractions, with an abnormal tilt of the body and head to one side).

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Store below 25°C.**
- Do not discard medicines into the wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer need. Taking these measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, maize starch, magnesium stearate, colloidal anhydrous silica, hypromellose, titanium dioxide, macrogol/PEG, iron oxide yellow (only in Donepezil Teva 10 mg tablets).

What the medicine looks like and the contents of the package:
Donepezil Teva 5 mg: A white, round and convex film-coated tablet, "DN 5" is debossed on one side and the other side is plain.
Donepezil Teva 10 mg: A yellow, round and convex film-coated tablet, "DN 10" is debossed on one side and the other side is plain.

The package contains 30 film-coated tablets.

Name of Manufacturer and License Holder and Address:
Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020

Revised in April 2024.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:
Donepezil Teva 5 mg: 159.50.34715
Donepezil Teva 10 mg: 159.51.34714

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