**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:**
Acetylcholine esterase inhibitors.
Acetylcholine is involved in the memory processes in the brain. Donepezil increases the amount of acetylcholine by slowing down its breakdown activity.
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 starting 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).
- 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 a 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, tell the doctor or pharmacist, since these medicines may affect the efficacy of Donepezil Teva.** In particular, if you are taking:
- 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.
- antibiotics, e.g., erythromycin and rifampicin.
- anti-fungal medicines, e.g., ketoconazole.
- anti-depressants, e.g., fluoxetine.
- 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 anaesthetics.
- Non-prescription medicines, including herbal remedies.

If you are due to undergo an operation that involves general anaesthesia, inform the anesthesiologist and the attending doctor that you are taking Donepezil Teva. Donepezil Teva may affect the amount of anaesthetic 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 has no effect on the action 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.

**Pregnancy**
There is not enough information about use of donepezil in pregnant women.
Animal studies have not shown a teratogenic effect (birth defects), but showed that there is toxicity before and after delivery. The risk during pregnancy in humans is unknown. Therefore, it is not recommended to use Donepezil Teva during pregnancy unless there is a clear need.

**Breast-feeding**
Donepezil is secreted into rat breast milk. It is not known whether donepezil is also secreted into human breast milk and there are no studies in breast-feeding women. Therefore, do not use Donepezil Teva when 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 dangerous machinery or tools. 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 dangerous machinery or tools.

**Important information about some of the ingredients of the medicine**
The medicine contains lactose. If you have been told by your doctor that you are sensitive 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. Always follow the doctor's or pharmacist's recommendation regarding how and when to take the medicine. Do not alter the dosage without instruction from the doctor.
**Do not exceed the recommended dose.**

**Duration of Donepezil Teva treatment**
Refer to the doctor from time to time to evaluate the treatment and assess your symptoms.

**Method of administration**
Take Donepezil Teva tablets whole with water before bedtime. 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 difficulty, loss of consciousness, fits or convulsions.

**If you forget 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.**

**Severe 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 sternum (occurs at a frequency of up to 1 user in 100).
- bleeding in the stomach or intestines. Manifested as coal-black stool or visible blood in the rectum (occurs at a frequency of up to 1 user in 100).
- convulsions or seizures (occur at a frequency of up to 1 user in 100).
- high fever with muscle stiffness, sweating or decreased level of consciousness [a disturbance called neuroleptic malignant syndrome (NMS)] (occurs at a frequency of up to 1 in 10,000 users).
- muscle weakness, muscle tenderness or pain, especially if you also 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 in 10,000 users).

**Additional side effects**

**Very common side effects (occur at a frequency of more than 1 user in 10):**
Diarrhoea, nausea, 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, vomiting, lack of appetite, 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, heart rhythm disturbances.

**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 waste water 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 its Address:**
Teva Pharmaceutical Industries Ltd.,
P.O.B. 3190, Petah-Tikva.

**Name of License Holder and its Address:**
Abic Marketing Ltd., P.O.B. 8077, Netanya.

The leaflet was revised in May 2021 according to MOH guidelines.

**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

teva DONE CTAB PL SH 130721