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
Tablets

Each tablet contains:
Donepezil HCl 5 mg

Donepezil Teva® 10 mg
Tablets

Each tablet contains:
Donepezil HCl 10 mg

For the list of inactive ingredients in the preparation, see section 6 - "Further Information".

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of 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.

This medicine is not intended for children.

1. WHAT IS THE MEDICINE INTENDED FOR?

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

Therapeutic group:
Inhibitors of the enzyme acetylcholinesterase.

2. BEFORE USING THE MEDICINE

☒ Do not use the medicine if:
there is a known sensitivity to any of its ingredients or to piperidine derivatives.

Special warnings regarding use of the medicine

❗ Inform the doctor before starting treatment if you are suffering, or have suffered in the past, from:
- a stomach or duodenal ulcer
- convulsions or seizures (epilepsy)
- any heart problem, including irregular, slow or fast heartbeat
- asthma or other chronic pulmonary disease
- liver inflammation (hepatitis)
- impaired kidney function
- difficulty passing urine
- If you are about to undergo surgery (including dental surgery), or any procedure requiring anesthesia, inform the anesthesiologist that you are taking this medicine, because it may increase the activity of the anesthetic.

❗ Additional warnings
- If you are sensitive to any food or medicine, inform the doctor before taking this medicine.
- The preparation contains lactose and may cause allergy in people sensitive to lactose.

❗ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

In particular, inform the doctor if you are taking the following medicines:
- Other medicines to treat Alzheimer's disease, such as galantamine
- Antidepressants (e.g., fluoxetine)
- Anticholinergics or medicines with anticholinergic activity (e.g., antispasmodics)
- Neuromuscular blockers (such as succinylcholine in surgery)
- Analgesics, such as aspirin and non-steroidal anti-inflammatory drugs (NSAIDs) (such as ibuprofen or diclofenac)
- Medicines to treat heart function (e.g., antiarrhythmics, beta blockers)
- Antiepileptics (e.g., carbamazepine, phenobarbitone, phenytoin)
- Antifungals (e.g., ketoconazole)
- Rifampicin (for tuberculosis)
- Antibiotics (such as erythromycin)
- General anesthetics – see special warnings in this section

❗ Use of the medicine and food
This medicine can be taken with or without food.

❗ Use of the medicine and alcohol consumption
Do not drink wine or alcoholic beverages during the course of treatment with this medicine, since it may change the effect of the medicine.

❗ Pregnancy and breastfeeding
If you are pregnant, planning to become pregnant, or are breastfeeding, consult the doctor before using the medicine.

❗ Use in children
This medicine is not intended for children.

❗ Driving and use of machinery
Use of this medicine may impair alertness, cause dizziness, tiredness or muscle cramps, and therefore requires that caution be exercised when driving a car, operating complicated machinery and in any activity that requires alertness.

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.

The dosage and treatment regimen will be determined by the doctor only.

The usual initial dosage is generally: one 5 mg tablet in the evening at bedtime. After approximately one month, the doctor will consider administration of one 10 mg tablet in the evening.

Use this medicine at specified time intervals as determined by the attending doctor.

The tablet cannot be halved, as there is no score line.

Do not exceed the recommended dose.

If you took an overdose, or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting without explicit instruction from the doctor!

Symptoms of overdose: nausea, drooling, sweating, slow heartbeat, low blood pressure (manifested by dizziness when switching from a sitting to standing position), breathing problems, loss of consciousness, seizures or convulsions.

If you forgot to take this medicine at the designated time, take the next dose at the usual time. Do not take two doses together to compensate for a forgotten dose.

Adhere to the treatment as recommended by the doctor, even if there is an improvement in your health condition. Do not stop treatment without consulting the doctor or pharmacist.

Do not take medicines in the dark! Check the label and 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 this medicine can 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 a doctor immediately if you experience any of the following effects - you may need urgent medical treatment:
- liver damage e.g., hepatitis, manifested by: nausea, lack of appetite, feeling generally unwell, fever, itching, yellow skin and eyes, dark urine (affect 1 to 10 in 10,000 users)
- duodenal or stomach ulcer, manifested by: stomach pains, indigestion (affect 1 to 10 in 1,000 users)
- bleeding in the stomach or intestines, manifested by bloody or black stools (affect 1 to 10 in 1,000 users)
- seizures or convulsions (affect 1 to 10 in 1,000 users)
- fever, muscle stiffness, sweating, loss of consciousness (affect less than 1 in 10,000 users)
- Muscle weakness, muscle tenderness or pain, particularly if at the same time you feel unwell, have high fever or dark urine. These effects may be caused by an abnormal muscle tissue breakdown (a condition called rhabdomyolysis), which can be life-threatening and lead to kidney damage.

Very common side effects – effects that occur in more than one user in ten:
- diarrhea
- nausea
- headaches

Common side effects – effects that occur in 1-10 users in 100:
- muscle cramps
- tiredness
- insomnia
- the common cold
- lack of appetite
- hallucinations
- nightmares
- aggressive behavior
- agitation
- fainting
- dizziness
- abdominal discomfort
- rash
- itching
- lack of control in passing urine
- pains
- tendency to have accidents (tendency to fall and get hurt)

Uncommon side effects – effects that occur in 1-10 users in 1,000:
- slow heartbeat

Rare side effects – effects that occur in 1-10 users in 10,000:
- stiffness, shaking and lack of control in body movements, especially of the face and tongue, and also of the limbs

If a side effect occurs, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in the leaflet, consult 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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.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 of children and/or infants to avoid poisoning.

Do not use the medicine after the expiry date that appears on the package. The expiry date refers to the last day of that month.

Store in a dry place, below 25°C.

Do not discard medicines in the wastewater or waste bin. Ask the pharmacist how to dispose of medicines that are not in use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Lactose anhydrous, microcrystalline cellulose, pregelatinized starch, hypromellose, magnesium stearate, purified water, polyvinyl alcohol, titanium dioxide, macrogol/PEG, talc, iron oxide yellow (only in the 10 mg).

Each Donepezil Teva 5 mg tablet contains 128.2 mg lactose.

Each Donepezil Teva 10 mg tablet contains 256.4 mg lactose.

What the medicine looks like and the contents of the package

Donepezil Teva 5 mg: White, film-coated, oval-shaped tablet, debossed with "93" on one side and "7320" on the other.

Donepezil Teva 10 mg: Yellow, film-coated, oval-shaped tablet, debossed with "93" on one side and "7321" on the other.

The package contains 30 film-coated tablets.

Manufacturer and license holder

Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petach Tikva.

This leaflet was checked and approved by the Ministry of Health in 03/2016

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Donepezil Teva 5 mg:
141.25.31460

Donepezil Teva 10 mg:
141.26.31461

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