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

The medicine is dispensed with a doctor's prescription only

Memorit 10

Tablets

Active ingredient and its quantity:
Each **Memorit 10** tablet contains:
Donepezil Hydrochloride 10 mg

Inactive and allergenic ingredients in the preparation: see in section 2 "Important information about some of the ingredients in this medicine" and in section 6 of the leaflet "Further information".

Read this 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 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.

1. WHAT IS THE MEDICINE INTENDED FOR?

To treat mild to moderate Alzheimer's disease dementia.

Therapeutic group: Acetylcholine esterase enzyme inhibitors.

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

This 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, to piperidine derivatives or to any of the additional ingredients contained in the medicine (see section 6 "Further Information" in this leaflet).

Special warnings regarding use of this medicine

Before treatment with **Memorit 10**, tell the doctor if you are suffering, or have suffered in the past, from:

- stomach or duodenal ulcers.
- seizures 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 your doctor if you are pregnant or think you might be pregnant.

Patients with kidney disease can use **Memorit 10**, but the doctor should be consulted.

Patients with mild to moderate liver disease can use **Memorit 10**, but the doctor should be consulted.

This medicine is not recommended for use in patients with a severe liver disease.

Children and adolescents

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

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 effectiveness of Memorit 10. Especially if you are taking:

- medicines for heart rhythm disturbances, such as amiodarone, sotalol.
- antidepressants, such as citalopram, escitalopram, amitriptyline, fluoxetine.
- medicines for mental disturbances, such as pimozide, sertindole, ziprasidone.
- antibiotics, such as clarithromycin, erythromycin, levofloxacin, moxifloxacin and rifampicin.
- antifungals, such as ketoconazole.
- other anti-Alzheimer's medicines e.g., galantamine.
- pain relievers or medicines for arthritis, e.g., aspirin, non-steroidal anti-inflammatory drugs (NSAIDs) (such as ibuprofen or diclofenac sodium).
- anticholinergic medicines, such as tolterodine.
- anti-convulsants (epilepsy) such as phenytoin or carbamazepine.
- medicines to treat heart diseases, e.g., quinidine or beta-blockers (such as propranolol and atenolol).
- muscle relaxants such as diazepam, succinylcholine.
- general anesthetics.
- non-prescription medications including medicinal herbs.

If you are due to undergo surgery that involves general anesthesia, inform the anesthesiologist and attending doctor that you are taking **Memorit 10**. **Memorit 10** may affect the required amount of anesthetic. Inform the doctor or pharmacist who your caregiver is. Your caregiver can help you take the medicines as needed.

Use of Memorit 10 and food

Food has no impact on the activity of the medicine.

Use of Memorit 10 and alcohol consumption

Do not drink alcohol while under treatment with **Memorit 10**. The alcohol may affect the activity of the medicine.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, consult a doctor before using **Memorit 10**.

Do not use **Memorit 10** while breastfeeding.

Driving and operating machines

Do not drive or operate dangerous machines while using the medicine as Alzheimer's disease may impair your ability to drive or operate dangerous machinery or tools. For your safety, you must not perform these activities unless your doctor has allowed you to do so.

Also, **Memorit 10** 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 in this medicine

This 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 **Memorit 10**.

3. HOW SHOULD YOU USE THE MEDICINE?

- Always use the preparation according to the doctor's instructions.
- Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation. The dosage and treatment regimen will be determined by the doctor only.

- **The usual dosage is generally:**
  The starting dosage is usually half a tablet of **Memorit 10** (5 mg) every night. After one month, the doctor may tell you to take **Memorit 10** (10 mg) every night.
  The strength of the medicine may change depending on the amount of time you are taking it and the doctor's recommendations.
- The maximal recommended dosage is 10 mg **Memorit 10** every night.
- **Do not exceed the recommended dose! Do not change the dosage without being instructed to do so by the doctor.**
  Adhere to the **Memorit 10** treatment regimen as recommended by the doctor.
- **Duration of Memorit 10 treatment:**
  During the course of treatment, refer to the doctor periodically to assess the symptoms and treatment.

Method of administration:

Take the **Memorit 10** tablet whole, with a little water, at bedtime.

In cases of sleep disturbances, including strange dreams, nightmares or insomnia, consider taking **Memorit 10** tablets in the morning.

If necessary, the tablet can be halved for immediate use. There is no information regarding crushing or chewing the tablet.

- **If you accidentally took a higher dosage** of **Memorit 10**, or if a child or someone else has accidentally swallowed the medicine, refer immediately to a 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 overdose of **Memorit 10** may include nausea and vomiting, salivation, sweating, slow heart rate, hypotension (dizziness while standing), breathing difficulty, loss of consciousness, seizures or convulsions.
- **If you forget to take the medicine:**
  If you forgot to take **Memorit 10** at the designated time, do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time and consult the doctor. If you forgot to take **Memorit 10** for a period longer than one week, consult the doctor before you resume taking **Memorit 10**. Adhere to the treatment regimen of **Memorit 10** as recommended by the doctor. Even if there is an improvement in you health, do not stop taking the medicine without consulting the doctor.
- **If you stop taking Memorit 10:**
  Do not stop taking the medicine unless the doctor has told you to do so. If you stop taking **Memorit 10**, the benefits of 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 Memorit 10, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of **Memorit 10** 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 a doctor immediately if the following serious side effects occur; you may need emergency medical care:

- Liver damage or hepatitis. The symptoms of hepatitis are: nausea and vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes and dark colored urine (appear at a frequency of up to one user in 1,000).
- Stomach or duodenal ulcers. The symptoms are: abdominal pain and discomfort (feeling of indigestion) in the abdominal area between the navel and the breast bone (appear at a frequency of up to one user in 100).
- Bleeding in the stomach or intestines, manifested by coal-black stools or visible blood from the rectum (appear at a frequency of up to one user in 100).
- Seizures or convulsions (appear at a frequency of up to one user in 100).
- High fever with muscle stiffness, sweating, or a lowered level of consciousness (a disorder called Neuroleptic Malignant Syndrome [NMS]) (appear at a frequency of up to one user in 10,000).
- Muscle weakness, muscle tenderness or pain, especially if accompanied by malaise, you have fever or dark urine. These signs may be caused by an abnormal condition of muscle breakdown which may be life-threatening and cause kidney problems (a condition called rhabdomyolysis) (appear at a frequency of up to one user in 10,000).
- Rapid, uneven pulse and fainting, which can be symptoms of a life-threatening condition known as Torsade de Pointes; the frequency can not be estimated from the available clinical data.

Additional side effects:

Very common side effects occur in more than one user in 10:

Diarrhea, headaches.

Common side effects occur at a frequency of up to one user in 10:

Muscle cramps, tiredness, insomnia, common cold, hallucinations (seeing and hearing things that do not exist), unusual dreams including nightmares, restlessness, aggressive behavior, fainting, dizziness, abdominal discomfort, rash, lack of control when passing urine, pain, accidents (patients are more prone to falls and injuries).

Uncommon side effects occur at a frequency of up to one user in 100:

Slow heart rate, increased salivation.

Rare side effects occur at a frequency of up to one user in 1,000:

Stiffness, tremors, involuntary movements especially of the face and tongue but also of the limbs.

Side effects of unknown frequency (effects whose frequencies have not been determined yet):

- Changes in heart activity which can be seen in an ECG - "prolonged QT interval".
- Increase libido, excessive sexuality.
- Pisa syndrome (characterized by involuntary muscle contraction, with an unusual 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

Additionally, you can report to "Unipharm Ltd".

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 in order 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 carton and blister package. The expiry date refers to the last day of that month.
- Store the medicine at a temperature below 25°C and in a place protected from light.
- Do not dispose of medicines in waste water or household waste. Ask the pharmacist how to dispose of medicines that you no longer need. These measures will help protect the environment.

6. FURTHER INFORMATION

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

Microcrystalline Cellulose, Lactose (anhydrous), Sodium Starch Glycolate, Magnesium Stearate, Opadry Y-1-7000.

Each **Memorit 10** tablet contains 80 mg lactose anhydrous.

What the medicine looks like and the contents of the package:

Memorit 10 tablets are film-coated, white, round, and biconvex, with a break line on one side.

Memorit 10 is packaged in trays (blisters), inserted in a carton package. Each package of **Memorit 10** contains 2, 7, 10, 14, 20, 28, 30 or 100 tablets.

Not all package sizes may be marketed.

Name of Registration holder and address: Unipharm Ltd., P.O. Box 21429, Tel Aviv, 6121301.

Name of Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: **Memorit 10**: 132 20 29786 03

Revised in September 2023 according to MOH guidelines.

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