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

The medicine is dispensed with a doctor's prescription only.

Memorit 5; 10

Tablets

Active ingredient and its quantity:
Each **Memorit 5** tablet contains:
Donepezil Hydrochloride 5 mg
Each **Memorit 10** tablet contains:
Donepezil Hydrochloride 10 mg

Other inactive ingredients: see section 6 of the leaflet.

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.

This medicine is intended for adults only.

1. WHAT IS THE MEDICINE INTENDED FOR?

To treat mild to moderate Alzheimer's disease-associated dementia.

Therapeutic group: Acetylcholine esterase 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.

2. BEFORE USING THE MEDICINE

☒ Do not use Memorit if:

- you are sensitive (allergic) to the active ingredient donepezil hydrochloride, to piperidine derivatives or to any of the other ingredients contained in the medicine (see section 6: "Further Information" in this leaflet).

Special warnings regarding use of this medicine:

Before treatment with the medicine, consult the doctor if you are suffering, or have suffered in the past, from:

- stomach or duodenal ulcers.
- fits or convulsions.
- heart disease (irregular or very slow heart rate).
- asthma or other chronic lung disease.
- liver problems.
- difficulty passing urine or mild kidney disease.

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

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

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

If any of the above conditions applies to you, **tell the doctor or pharmacist** before starting treatment with **Memorit**.

Inform your doctor or pharmacist about your caregiver. The caregiver will be able to help you take the medicines as necessary.

❗ 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 effectiveness of Memorit.

In particular, inform the doctor or pharmacist if you are taking the following medicines:

- other anti-Alzheimer's medicines e.g., galantamine.
- pain killers or medicines for arthritis, e.g., aspirin, non-steroidal anti-inflammatory drugs (NSAIDs) (such as ibuprofen or diclofenac sodium).
- anticholinergics such as tolterodine.
- antibiotics e.g., erythromycin and rifampicin.
- anti-fungal medicines e.g., ketoconazole, itraconazole.
- anti-depressants e.g., fluoxetine.
- anti-convulsants (epilepsy) e.g., phenytoin or carbamazepine.
- medicines to treat heart conditions e.g., quinidine or beta-blockers (such as propranolol and atenolol).
- muscle relaxants e.g., diazepam, succinylcholine.
- general anesthetics.

❗ Surgery and tests while using Memorit

If you are due to undergo surgery (including dental surgery) or any procedure that involves anesthesia, inform the anesthesiologist and attending doctor that you are taking **Memorit**. **Memorit** may affect the required amount of anesthetic.

❗ Use of Memorit and food

Food has no impact on the activity of the medicine.

❗ Use of Memorit and alcohol consumption

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

❗ Driving and operating machines

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** may cause tiredness, dizziness and muscle cramps. If these effects occur, do not drive or operate dangerous machinery or tools.

❗ Pregnancy and breastfeeding

Do not use **Memorit** when breastfeeding. Consult the doctor if you are pregnant or might be pregnant.

❗ Important information about some of the ingredients in this medicine

This medicine contains lactose. If you are sensitive to certain sugars, consult the doctor before starting treatment with **Memorit**.

3. HOW SHOULD YOU USE THE MEDICINE?

- Always use 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 dosage is generally:**
  The starting dosage is usually **Memorit 5** (5 mg) every night. After one month, the doctor may tell you to take **Memorit 10** (10 mg) every night. Take a whole **Memorit** tablet with a little water at bedtime.
  When necessary, the tablet can be halved for immediate use. There is no information about crushing or chewing the tablet.
  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** 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** treatment regimen as recommended by the doctor.
- **Duration of Memorit treatment:**
  Your doctor or pharmacist will recommend a **Memorit** treatment duration for you. During the course of treatment, have yourself checked by the doctor periodically to assess the symptoms and treatment.
- **If you accidentally took a higher dosage** of **Memorit**, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. Signs of overdose of **Memorit** include nausea and vomiting, salivation, sweating, slow heart rate, hypotension (dizziness when standing up), breathing difficulty, loss of consciousness, seizures or convulsions.
  Do not take more than one tablet a day.
- **If you forget to take the medicine:**
  If you forgot to take **Memorit** at the required time, do not take a double dose. Take the next dose the next day as usual. If you forgot to take **Memorit** for a period longer than one week, consult the doctor before you resume taking **Memorit**.
- **If you stop taking Memorit:**
  Do not stop taking the medicine unless the doctor has told you to do so. If you stop taking **Memorit**, the benefits of treatment will gradually disappear.

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, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of **Memorit** may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Refer to a doctor immediately if the following serious side effects occur; you may need emergency medical care:

Uncommon side effects (effects that occur in 1-10 in 1,000 patients):

- 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).
- Stomach or duodenal ulcers. The symptoms are: abdominal pain and discomfort (feeling of indigestion) in the abdominal area between the navel and the breastbone.
- Bleeding in the stomach or intestines, manifested by black stools or visible blood in the anal region.
- Seizures or convulsions.

Rare side effects (effects that occur in 1-10 in 10,000 users):

- Neuroleptic malignant syndrome (NMS). The signs of NMS include: high fever, muscle stiffness, sweating or reduced consciousness.
- Liver damage, such as: jaundice (hepatitis). The symptoms are: nausea and vomiting, lack of appetite, general unwell feeling, fever, itching, yellowing of the skin and eyes, and dark-colored urine.

Additional side effects:

Very common side effects (effects that occur in more than one user in 10):
Diarrhea, nausea and vomiting, headache.

Common side effects (effects that occur in 1-10 in 100 users):
Muscle cramps, tiredness, insomnia, common cold, loss of appetite, hallucinations, unusual dreams including nightmares, restlessness, aggressive behavior, fainting, dizziness, abdominal discomfort, rash, itching, lack of control when passing urine, pain, accidents (patients are more prone to falls and injuries).

Uncommon side effects (effects that occur in 1-10 in 1,000 users):
Slow heart rate.

Rare side effects (effects that occur in 1-10 in 10,000 users):
Stiffness, tremors, involuntary movements especially of the face and tongue but also of the limbs.

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.

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.
Alternatively, 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 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 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 5** tablet contains 40 mg lactose anhydrous.
Each **Memorit 10** tablet contains 80 mg lactose anhydrous.

What the medicine looks like and the contents of the package:
Memorit tablets are film-coated, white, round, and biconvex, with a scoreline on one side.
Memorit is packaged in trays (blisters), inserted in a carton package. Each package of **Memorit** contains 2, 7, 10, 14, 20, 28, 30, 100 tablets.
Not all package sizes may be marketed.

Registration holder: Unipharm Ltd., P.O.Box 21429, Tel Aviv, 6121301.

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

This leaflet was checked and approved by the Ministry of Health in March 2016 and was updated in accordance with the Ministry of Health guidelines in: July 2018.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Memorit 5: 132 21 29785 02
Memorit 10: 132 20 29786 03

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