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

The medicine is dispensed with a doctor's prescription only

# MEMOX TABLETS 10, 20 mg

**Composition:**

Each **Memox 10** tablet contains:

Memantine hydrochloride 10 mg

Each **Memox 20** tablet contains:

Memantine hydrochloride 20 mg

**Inactive and allergenic ingredients in the preparation:** see section 2 "Before using 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.

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 ailment is similar.

## 1. WHAT IS THE MEDICINE INTENDED FOR?

**Memox** is intended for the treatment of moderate to severe Alzheimer's disease.

**Memox** belongs to a group of medicines for the treatment of dementia. The memory loss characteristic of Alzheimer's disease is caused by disruption of the transmission of nerve signals in the brain. There are receptors in the brain called NMDA receptors. These receptors are involved in transmission of nerve signals which are important for learning and memory. **Memox** acts on NMDA receptors, thereby improving transmission of nerve signals and memory.

**Therapeutic group:** NMDA receptor antagonist.

## 2. BEFORE USING THE MEDICINE

**Do not use the medicine if:**

You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (see list of inactive ingredients in section 6).

**Special warnings regarding use of the medicine**

**Before treatment with Memox, tell the doctor if:**

- You have a history of epilepsy (epileptic attacks).
- You recently suffered from a myocardial infarction (heart attack), or if you are suffering from heart failure or from uncontrolled hypertension. In the above-mentioned situations, the doctor will carefully monitor the treatment with the medicine and will regularly assess its effectiveness.
- You suffer from renal impairment (kidney problems). The doctor will have to closely monitor your kidney function and adapt the dosage, if needed.
- You are suffering from states of renal tubulary acidosis (RTA, an excess of acid-forming substances in the blood due to reduced kidney function), or from severe infections of the urinary tract, the doctor may need to adjust the dosage of the medicine to your condition.

Avoid concomitant use of **Memox** and the following medicines:

- amantadine (for the treatment of Parkinson's disease)
- ketamine (a substance used as general anesthesia)
- dextromethorphan (a medicine to treat cough)
- other NMDA antagonists

**Children and adolescents**

**Memox** is not recommended 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.** In particular, inform the doctor or pharmacist if you are taking the following medicines, since **Memox** may change their effects and the doctor may have to adjust the dosage:

- amantadine, ketamine, dextromethorphan (see in section 2 "Special warnings regarding use of the medicine").
- dantrolene, baclofen.
- cimetidine, ranitidine, procainamide, quinidine, quinine, nicotine.
- hydrochlorothiazide (or any combination with hydrochlorothiazide).
- anticholinergics (generally used to treat movement disorders and intestinal cramps).
- medicines to treat epilepsy (to prevent and relieve seizures).
- barbiturates (generally used to induce sleep).
- dopaminergic agonists, such as L-dopa, bromocriptine.
- neuroleptics (to treat mental disorders).
- oral anticoagulants.

If you seek treatment in a hospital, inform the doctor that you are taking **Memox**.

**Use of the medicine and food**

The medicine can be taken with or without food. Inform your doctor if you recently made or plan to make significant changes in your daily diet (e.g., switching from a regular to a vegetarian diet), since the doctor may have to adjust the dosage of the medicine accordingly.

**Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you are pregnant or plan to become pregnant, consult the doctor or pharmacist before using this medicine.

**Pregnancy**

Use of memantine in pregnant women is not recommended.

**Breastfeeding**

Do not breastfeed if you are taking **Memox**.

**Driving and operating machinery**

The doctor will tell you if your medical condition allows you to safely drive or operate machinery.

In addition, **Memox** may change your responsiveness; therefore, driving and operating machinery is not recommended.

**Important information about some of the ingredients of the medicine**

**Memox** contains lactose. If you have been told by your doctor that you have a sensitivity to certain sugars, consult the doctor before using the medicine. See section 6 "Further information".

## 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 recommended dosage is generally:

The dosage recommended for adults and the elderly – 20 mg a day.

To reduce the risk of side effects, take the dosage gradually according to the following program:

| | |
|---|---|
| Week 1: | 5 mg |
| Week 2: | 10 mg |
| Week 3: | 15 mg |
| Week 4 and on: | 20 mg |

The starting dose is half a **Memox 10** tablet per day for the first week.

In the second week, one **Memox 10** tablet per day.

In the third week, one and a half **Memox 10** tablets per day.

From the fourth week and on, one **Memox 20** tablet or two **Memox 10** tablets per day.

The dosage for patients with impaired kidney function:

In patients with mild renal impairment (creatinine clearance 50-80 ml/min), there is no need to adjust the dosage.

In patients with moderate renal impairment (creatinine clearance 30-49 ml/min), the daily dosage is 10 mg per day. If you tolerate the medicine after 7 days of treatment, the dosage can be increased to 20 mg per day.

In patients with severe renal impairment (creatinine clearance 5-29 ml/min), the daily dosage is 10 mg per day.

**Do not exceed the recommended dose.**

**Instructions for use:** Swallow the tablet with a little water.

Take the medicine once a day. Take the medicine at the same time every day.

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

**If you accidentally take a higher dosage,** refer to a doctor or seek medical assistance. Taking an overdose generally will not cause harm, but you may experience side effects (see section 4 "Side effects" ).

If you took an overdose 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.

**If you forgot to take the medicine** at the required time, do not take a double dose. Take the next dose at the regular time and consult the doctor.

Use this medicine at set intervals, as determined by the attending doctor.

Adhere to the 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 a doctor.

**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 **Memox** 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. The observed side effects are mild to moderate.

**Common side effects (effects that occur in 1-10 users in 100):**

Headache, sleepiness, constipation, increased liver function test results, dizziness, balance disturbances, shortness of breath, hypertension, allergic reaction to the medicine (hypersensitivity).

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

Fatigue, fungal infections, confusion, hallucinations, vomiting, walking disturbances, heart failure, vein thrombosis.

**Very rare side effects (effects that occur in less than one user in 10,000):**

Seizures.

**Side effects of unknown frequency (effects whose frequency has not yet been determined):**

Pancreatitis, hepatitis and psychotic reactions.

Alzheimer's disease has also been linked to depression, suicidal thoughts and suicide. These events have also been reported in patients taking memantine.

**If one of the 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 "Reporting 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, should 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 package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store the medicine at a temperature below 25°C and in a place protected from light.
- Do not dispose of the medicine in the household waste bin or toilet. Consult the pharmacist as to how to dispose of medicines that are no longer needed or have expired.

## 6. FURTHER INFORMATION

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

Microcrystalline Cellulose, Lactose Anhydrous, Magnesium Stearate, Opadry White.

The preparation contains lactose and may cause allergy in people sensitive to lactose.

Each **Memox 10** tablet contains 94 mg lactose (as anhydrous).

Each **Memox 20** tablet contains 188 mg lactose (as anhydrous).

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

**Memox Tablets** are packaged in trays (blisters) which are inserted into a carton box. Each **Memox** package has 7, 14, 15, 21, 28, 30 or 56 tablets. Not all package sizes may be marketed.

**Memox 10** are circular, film-coated, white, biconvex tablets with a score line on one side.

**Memox 20** are oblong, film-coated, white, biconvex tablets with a score line on one side.

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

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

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

**Memox 10:** 133 16 31117 02

**Memox 20:** 146 09 32965 01

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