

The dispensing of this medicine requires a doctor's prescription

MEMOX 10;20

TABLETS

Composition:

Each Memox 10 tablet contains: Memantine Hydrochloride 10 mg

Each Memox 20 tablet contains: Memantine Hydrochloride 20 mg

Inactive ingredients: See Section 6 'Additional Information'.

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

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

This medicine is not intended for children and adolescents under 18 years old.

1. What is this medicine intended for?

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

Memox belongs to a class of drugs that are used to treat dementia. Memory loss that is typical of Alzheimer's disease is caused by a disruption in transmission of neural signals in the brain.

In the brain there is a type of receptors, called NMDA receptors. These receptors are involved in transmitting neural signals that are important to learning and memory. By acting on NMDA receptors, Memox improves neural signal transmission and memory.

Therapeutic group: NMDA receptor antagonist.

2. Before using this medicine

Do not use this medicine if:

You are sensitive (allergic) to the active ingredient or to any of the other ingredients that this medicine contains (see Section 6 for a list of inactive ingredients).

Special warnings about using this medicine

▲ Before using Memox, tell your doctor if:

- You have a history of epilepsy (epileptic seizures)
- You are suffering, or have suffered in the past, from impaired function of the heart and/or vascular system (heart attack, heart failure, hypertension).

In any of the conditions listed above, your doctor will carefully monitor your treatment with this medicine, and will regularly evaluate its efficacy.

- You are suffering, or have suffered in the past, from impaired kidney function. Your doctor will have to carefully monitor your kidney function and adjust the dose if necessary.
- You have recently made or intend to make extreme changes in your daily diet (such as shifting from a regular diet to a vegetarian diet), or you consume large quantities of antacids.
- You are hospitalized. It is important to inform the doctor at the hospital that you are taking Memox.

Avoid taking the following medicines while taking Memox:

- Amantadine (for treating Parkinson's disease)
- Ketamine (a general anesthetic)
- Dextromethorphan (a cough medicine)
- Other NMDA antagonists

If you are taking or have recently taken other medicines, including nonprescription medications and nutritional supplements, tell your doctor or pharmacist. In particular tell the doctor or pharmacist if you are taking:

- Amantadine, ketamine, dextromethorphan (see section 'Special warnings about using this medicine')
- Dantrolene, baclofen (antispastic)
- Cimetidine, ranitidine, procainamide, quinidine, quinine, nicotine
- Hydrochlorothiazide
- Anticholinergic medicines (usually used to treat involuntary movements and intestinal colic)
- Medicines for treating epilepsy
- Barbiturates (sedatives or sleeping pills)
- Dopamine agonists such as L-DOPA, bromocriptine (for treating Parkinson's disease)
- Neuroleptics (for treating mental disorders)
- Anticoagulant medicines

Using the medicine and food

You can take this medicine with or without food.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to get pregnant consult your doctor or pharmacist before taking this medicine.

Pregnancy

Memox is not recommended for pregnant women.

Breast-feeding

Do not breastfeed if you are taking Memox.

Driving and using machines

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

In addition, do not drive, or operate dangerous machines while using this medicine, because your alertness and response time may be affected by the medicine.

3. How to use this medicine?

Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure.

Your doctor will determine your dose and how you should take the medicine. The recommended dose is usually:

Recommended dose for adult and elderly patients: 20 mg/day.

In order to reduce the risk of side effects, gradually increase the dose according to the following program:

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

The initial dose is half a tablet of Memox 10 once a day for the first week.

During the second week, one Memox 10 tablet once a day.

During the third week, one and a half tablets of Memox 10 once a day.

From the fourth week onward, one Memox 20 tablet or two Memox 10 tablets once a day.

Dose for patients with impaired kidney function:

In patients with mild renal failure (creatinine clearance 50-80 ml/min), no adjustment of the dose is necessary.

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

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

Do not exceed the recommended dose.

Directions for use: Swallow the medicine with some water.

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

You may crush or split the tablets if necessary.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, go immediately to a hospital emergency room and bring the medicine package with you.

Usually, taking an overdose does not do any harm, but you may experience side effects (see section 'Side effects').

If you forget to take this medicine at the scheduled time, wait and take the next dose at the regular time, but never take two doses together!

Take this medicine at regular intervals as your attending doctor has prescribed.

Persist with the treatment as recommended by the doctor. Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose each time you take the medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or the pharmacist.

4. Side effects

Like all medicines, taking **Memox** may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Common side effects (appear in up to 1:100 patients):

Dizziness, balance disorders, headache, constipation, sleepiness, hypertension, elevated liver function test results, shortness of breath, allergic reaction to the medicine.

Uncommon side effects (appear in up to 1:1000 patients):

Hallucinations, confusion, fatigue, walking disorders, vomiting, fungal infections, venous thrombosis, heart failure.

Rare side effects (appear in less than 1:1000 patients):

Seizures.

Side effects of unknown frequency: Psychotic reactions, pancreatitis, hepatitis.

Alzheimer's disease is also associated with depression, suicidal ideation, and suicide. Such events have also been reported in patients who were taking Memox.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health (MoH) by following the link 'Reporting Side Effects of Medication' on the MoH home page which links to an online form for reporting side effects. You can also report to [Unipharm company](#).

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of reach of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store below 25°C and in a place protected from light.

6. Additional information

In addition to the active ingredient this medicine also contains:

Microcrystalline cellulose, lactose anhydrous, magnesium stearate, opadry white.

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

Memox tablets are packed in blister trays in a cardboard box. There are 56 tablets in each package of **Memox 10**, There are 28 tablets in each package of **Memox 20**.

Memox 10 are round, white, film-coated, bi-convex tablets with a score line on one side.

Memox 20 are oval, white, film-coated, bi-convex tablets with a score line on one side.

Registration holder:

Unipharm Ltd., P.O.B. 21429, Tel-Aviv 6121301.

Manufacturer name and address:

Trima Ltd., Kibbutz Maabarot, Israel.

This leaflet was reviewed and approved by the Ministry of Health in: July 2016

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

Memox 10: 133 16 31117 01

Memox 20: 146 09 32965 00

 **unipharm ltd.**

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