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

The medicine is dispensed with a doctor's prescription only

Memantine Teva®

Tablets

Composition

Each tablet contains:
Memantine Hydrochloride 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 ailment is similar.

1. WHAT IS THIS MEDICINE INTENDED FOR?

This medicine is intended to treat moderate to severe Alzheimer's disease.

Therapeutic group

NMDA (N-methyl-D-aspartate) receptor antagonist

2. BEFORE USING THE MEDICINE

☒ Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient or to any of the other ingredients in the medicine (see the list of inactive ingredients in section 6)
- you are suffering from severe kidney dysfunction
- Do not take this medicine together with the medicines:
  - amantadine
  - ketamine
  - dextromethorphan
  - other medicines from the NMDA antagonist group
- you are pregnant or breastfeeding

Special warnings regarding use of the medicine

! Before treatment with Memantine, tell the doctor if:

You are sensitive to any food or medicine.

! Do not use this medicine without consulting the doctor before commencing treatment if:

- You are suffering, or have suffered in the past, from impaired function of:
  - the heart or blood vessels (heart attack, heart failure, high blood pressure)
  - severely impaired liver function
- You have epilepsy, a history of epilepsy, a history of convulsions or if you have risk factors for epilepsy

In the conditions mentioned above, the doctor will carefully monitor the treatment with the medicine and will regularly assess its efficacy.

- If you are suffering, or have suffered in the past, from impaired kidney function, the doctor will have to carefully monitor your kidney function and adjust the dosage, if necessary.
- You have undergone drastic changes in your diet, such as: transition to vegetarianism, consumption of large quantities of antacids.

! If you are hospitalized, it is important to inform the doctor at the hospital that you are taking Memantine.

! 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:
amantadine, ketamine, dextromethorphan – do not take these medicines with Memantine (see section "Do not use this medicine if").

- medicines that affect the central nervous system (e.g., sedatives, hypnotics, medicines for Parkinson's, for epilepsy and convulsions).
- neuroleptic medicines (to treat mental disorders)
- dopamine agonists such as L-DOPA, bromocriptine
- barbiturates (sedatives or hypnotics)
- hydrochlorothiazide
- cimetidine
- ranitidine
- procainamide
- quinidine
- quinine
- nicotine
- dantrolene, baclofen (for spasms)
- anticoagulants
- anticholinergics (usually medicines against intestinal hypermotility or cramps)

If you are hospitalized, it is important to inform the doctor at the hospital that you are taking Memantine.

! Use of the medicine and food

This medicine can be taken with or without food.

! Pregnancy and breastfeeding

Do not use this medicine if you are pregnant or breastfeeding.

! Use in children

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

! Driving and use of machinery

The doctor will explain to you if your medical condition allows you to drive or operate machinery safely. Use of this medicine may impair your reaction time and therefore requires that caution be exercised when driving a car and when operating dangerous machinery.

! Important information about some of the ingredients of the medicine

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

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this 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 dosage is generally:

The usual dosage:
Adults and the elderly - 20 mg per day.

Initial dosage:
In order to reduce the risk of side effects, the dosage should be gradually increased, as per the following program:

Week 1	5 mg per day (half a tablet)
Week 2	10 mg per day (one tablet)
Week 3	15 mg per day (one and a half tablets)
Week 4 and on	20 mg per day (2 tablets)

The initial dosage is half a tablet per day for the first week.
In the second week, one tablet per day.
In the third week, one and a half tablets per day.
From the fourth week and on, two tablets per day.

Dosage for patients with moderate kidney function
According to the doctor's recommendation. In addition, kidney function monitoring tests should be performed.

Do not exceed the recommended dose.

Instructions for use of the medicine:

- Swallow the tablet with a little water.
- The tablet can be halved on the score line.
- Take the medicine every day at the same time.

Tests and follow-up

During the course of treatment with this medicine, kidney function tests should be performed.

If you accidentally 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.

If you forgot to take this medicine at the required time, wait and take the next dose at the usual time. Never take two doses together.

Adhere to the treatment as recommended by the doctor. Even if there is an improvement in your health condition, do not discontinue 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 Memantine 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.

Side effects that occur frequently:

Headache, sleepiness, constipation, high liver function values, dizziness, balance problems, shortness of breath, increased blood pressure, hypersensitivity to the medicine.

Side effects that occur infrequently:

Tiredness, fungal infections, confusion, hallucinations, vomiting, gait disorders, heart failure, venous blood clots.

Rare/very rare side effects:

Convulsions

Side effects of unknown frequency:

Psychotic reactions, inflammation of the pancreas, inflammation of the liver (hepatitis).

Alzheimer's disease has been associated with depression, suicidal thoughts and suicide. These effects have been reported in patients who were treated with Memantine.

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.

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 without explicit instruction from 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.
- Do not discard medicines in the waste water or waste bin. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.
- Store in a dry place, below 25°C.

6. FURTHER INFORMATION

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

Lactose monohydrate, Microcrystalline cellulose, Croscarmellose sodium, Magnesium stearate, Colloidal silica anhydrous, Povidone, Titanium dioxide, Hypromellose, Polyethylene glycol, Polysorbate 80.

Each tablet contains 140 mg lactose and 1.17-1.71 mg sodium.

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

The package contains white, capsule-shaped tablets:
There is a score line on one side of the tablet. The other side of the tablet has a score line, with "M" debossed on the left side of the line and the number "10" on the right side of the line.

Manufacturer and license holder:

Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petah Tikva 49131

This leaflet was checked and approved by the Ministry of Health in June 2014.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 140.41.31551.00/11

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