

MEMXA 10MG TABLET

Memantine hydrochloride 10mg eq. to Memantine 8.31mg

What is in this leaflet

1. What *MEMXA 10mg Tablet* is used for
2. How *MEMXA 10mg Tablet* works
3. Before you use *MEMXA 10mg Tablet*
4. How to use *MEMXA 10mg Tablet*
5. While you are using it
6. Side effects
7. Storage and Disposal of *MEMXA 10mg Tablet*
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What *MEMXA 10mg Tablet* is used for
MEMXA 10 belongs to a group of medicines known as anti-dementia medicines.

MEMXA 10 is used for the treatment of patients with moderate to severe Alzheimer's disease.

How *MEMXA 10mg Tablet* works

Memory loss in Alzheimer's disease is due to a disturbance of message signals in the brain. The brain contains so-called N-methyl-D-aspartate (NMDA)-receptors that are involved in transmitting nerve signals important in learning and memory. *MEMXA 10* belongs to a group of medicines called NMDA-receptor antagonists. *MEMXA 10* acts on these NMDA-receptors improving the transmission of nerve signals and the memory.

Before you use *MEMXA 10mg Tablet*

- When you must not use it

If you are allergic (Hypersensitive) to Memantine hydrochloride or any of the other ingredients of this medicine (listed in *Ingredients*).

Pregnancy and breast-feeding

Ask your doctor or pharmacist before taking any medicine.

Tell your doctor if you are pregnant or planning to become pregnant. The use of Memantine in pregnant women is not recommended.

Women taking *MEMXA 10mg Tablet* should not breast-feed.

Children and adolescents

MEMXA 10mg Tablet is not recommended for children and adolescents under the age of 18 years.

- Before you start to use it

Talk to your doctor or pharmacist before taking *MEMXA 10mg Tablet*:

- If you have a history of epileptic seizures
- If you have recently experienced a myocardial infarction (heart attack), or if you are suffering from congestive heart failure or from an uncontrolled hypertension (high blood pressure).

In these situations the treatment should be carefully supervised, and the clinical benefit of *MEMXA 10mg Tablet* is assessed by your doctor on a regular basis.

If you suffer from renal impairment (kidney problems), your doctor should closely monitor your kidney function and if necessary adapt the Memantine doses accordingly.

- Taking other medicines

Tell your doctor if you are taking, have recently taken or might take any other medicines.

In particular, *MEMXA 10mg Tablet* may change the effects of the following medicines and their dose may need to be adjusted by your doctor:

- The use of medicinal products called Amantadine (for the treatment of Parkinson's disease), Ketamine (a substance generally used as an anesthetic), Dextromethorphan (generally used to treat cough) and other NMDA-antagonist at the same time should be avoided.
- Dantrolene, Baclofen
- Cimetidine, Ranitidine, Procainamide, Quinidine, Quinine, Nicotine
- Hydrochlorothiazide (or any combination with Hydrochlorothiazide)
- Anticholinergics (substances generally used to treat movement disorders or intestinal cramps)

- Anticonvulsants (substances used to prevent and relieve seizures)
- Barbiturates (substances generally used to induce sleep)
- Dopaminergic agonist (substances such as L-dopa, Bromocriptine)
- Neuroleptics (substances used in the treatment of mental disorders)
- Oral anticoagulants

How to use *MEMXA 10mg Tablet*

- How much to use

Oral

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

The recommended dose of *MEMXA 10mg Tablet* for adults and elderly patient is 20mg once a day.

In order to reduce the risk of side effects this dose is achieved gradually by the following daily treatment scheme:

Week 1	Half a 10mg tablet
Week 2	One 10mg tablet
Week 3	One and a half 10mg tablet
Week 4 and beyond	Two 10mg tablets once a day

The usual starting dose is half a 10mg tablet once a day (5 mg once a day) for the first week. This is increased to one 10mg tablet once a day in the second week and to 1 and a half 10mg tablets once a day (15mg once a day) in the third week. From the fourth week on, the usual dose is two 10mg tablets once a day.

Dosage in patients with impaired kidney function

If you have impaired kidney function, your doctor will decide upon a dose that suits your condition. In this case, monitoring of your kidney function should be performed by your doctor at specified intervals.

Administration

MEMXA 10mg Tablet should be administered orally once a day. To benefit from your medicine you should take it regularly every day at the same time of the day.

- When to use it

Always take this medicine exactly as your doctor has told you. The tablets should be swallowed with a little water. The tablets can be taken with or without food.

- How long to use it

Continue to take *MEMXA 10mg Tablet* as long as it is of benefit to you. Your doctor should assess your treatment on a regular basis.

- If you forget to use it

If you find you have forgotten to take your dose of *MEMXA 10mg Tablet*, wait and take your next dose at the usual time.

Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

In general, taking too much *MEMXA 10mg Tablet* should not result in any harm to you. You may experience increase symptoms as described in section Side effects.

If you take a large overdose of *MEMXA 10mg Tablet*, contact your doctor or get medical advice as you may need medical attention.

While you are using it

- Things you must do

Ask your doctor or pharmacist for advice before taking any medicine.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you go into hospital, let your doctor know that you are taking *MEMXA 10mg Tablet*.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- Things you must not do

Do not stop treatment suddenly or change the recommended dose without talking to your doctor first.

- Things to be careful of

Driving and using machines

Your doctor will tell you whether your illness allows you to drive and to use machine safely. Also, *MEMXA 10mg Tablet* may change your reactivity, making driving or operating machinery inappropriate.

MEMXA 10mg Tablet with food and drink

You should inform your doctor if you have recently change or intend to change your diet substantially (e.g. from normal diet to strict vegetarian diet) your doctor may need to adjust the dose of your medicine.

If you are suffering from states of renal tubular acidosis (RTA, an excess of acid-forming substances in the blood due to renal dysfunction (poor kidney function)) or severe infections of the urinary tract (structure that carries urine), as your doctor may need to adjust the dose of your medicine.

Side effects

Like all medicines, *MEMXA 10mg Tablet* can cause side effects, although not everybody gets them. Most commonly reported side effects listed below:

Headache, sleepiness, constipation, and dizziness, high blood pressure. Alzheimer's disease has been associated with depression, suicidal ideation and suicide.

These events have been reported in patients treated with *MEMXA 10mg Tablet*. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of *MEMXA 10mg Tablet*

- Storage

Store at temperature of not more than 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

White, centrally, tapered oblong, biconvex, film coated tablet with engraved MMT on one side and scored on the other.

- Ingredients

- Active ingredient

- Memantine hydrochloride 10mg eq. to Memantine 8.31mg

- Inactive ingredients

Silicified microcrystalline cellulose (Prosolv SMCC 90), Mannitol, Croscarmellose sodium, Edetate disodium, sodium metabisulfite, Talc, Magnesium stearate, hypromellose (Methocel E15 LV Premium/ HPMC 2910), Titanium dioxide, Polyethylene glycol (PEG 400), Butylated hydroxytoluene, Isopropyl alcohol, Methylene chloride and purified water

- MAL number:

MAL17117029AZ

Manufacturer

UNISON LABORATORIES CO., LTD.
39 Moo 4, Klong Udomcholjorn,
Muang Chachoengsao,
Chachoengsao 24000 Thailand.

Product Registration Holder

MEDISPEC (M) SDN BHD
B-1-07, Jalan SS 25/22,
Taman Mayang,
47301 Petaling Jaya, Selangor, Malaysia

Date of revision

12/09/2023

Serial Number

NPRA(R2/1)230911/1138