MEMENTOR TABLETS

Memantine Hydrochloride 10 mg

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What Mementor is used for?

Mementor contains Memantine Hydrochloride. It is used for treatment of patients with moderate to severe Alzheimer's disease.

How Mementor works

Memantine Hydrochloride belongs to a group of medicines known as antidementia medicines. Memory loss in Azheimer'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. Memantine Hydrochloride belongs to group of medicines called NMDA- receptor antagonists. Mementor acts on these NMDA-receptors improving the transmission of nerve signals and memory.

Before you use Mementor

When you must not use it

If you are allergic (hypersensitive) to Memantine hydrochloride, or any other ingredients of mementor filmcoated tablets

<u>Before you start to use it</u> <u>Talk to your doctor or pharmacist</u> before taking Memantor

- If you have a history 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 Mementor reassessed by your doctor on a regular basis.

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

The use of medicinal products called amantadine (for the treatment of Parkinson's disease), ketamine (a substance generally used as an anaesthetic), dextromethorphan (generally used to treat cough) and other NMDA-antagonists at the same time should be avoided.

Mementor is not recommended for children and adolescents under the age of 18 years

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular, Mementor may change the effects of the following medicines and their dose may need to be adjusted by your doctor.

- Amantadine, kitamine, dextromethorphan
- 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 agonists (substances such as L-dopa, bromocriptine)
- neuroleptics (substances used in the treatment of mental disorders)
- oral anticoagulants

If you go into hospital, let your doctor know that you are taking Mementor.

How to use Mementor

How much to use

Always take Mementor exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The recommended dose of Mementor for adults and elderly patients 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 10 mg tablet
week 2	one 10 mg tablet
week 3	one and a half 10 mg
	tablets
week 4	two 10 mg tablets once
and beyond	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 you condition. In this case, monitoring of your kidney function should be performed by your doctor at specific intervals.

When to use it

It should be taken same time every day.

How long to use it

Continue to take Mementor as long as it is benefits to you. Your doctor should access your treatment on a regular basis.

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If you forget to use it

If you find you forgotten to take your dose of Mementor, 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 Mementor should not result in any harm to you. You may experience increased symptoms as described section "side effects" If you take a larger overdose of Mementor, contact your doctor or get medical advice, as you may need

While you are using Mementor

Things you must do

medical attention.

- Mementor should be administered orally once a day.
- The tablets can be taken with or without food.
- You should try to take your daily dose at about same time each day.
- You should inform your doctor if you have recently changed or intend to change your diet substantially (e.g from normal diet to strict vegetarian diet) or if you are suffering from states of renal tubular acidosis (RTA, an excess of an 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.

Things you must not do

- Your doctor will tell you whether your illness allows you to drive and to use machines safely
- Also, Mementor may change your reactivity, making driving or operating machinery inappropriate.

Things to be careful of

- Stop taking Mementor before you become pregnant or as soon as you know you are pregnant.
- Tell your doctor if you are breast feeding or about to start breast feeding. Mementor is not recommended for mothers who are breast feeding, and your doctor may choose another treatment for you if you wish to breast feed
- Driving and using machines
 Memantine has minor or
 moderate influence on the ability
 to drive and use machines, if
 you feel dizziness or headache,
 do not drive or use machines and
 contact your doctor
 immediately.

Side effects

Like all medicines, Mementor 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 Mementor.

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 calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of Mementor

Storage

 Do not use Mementor after the expiry date which is stated on the carton and the blister strip.
 The expiry date refers to the last day of that month.

- Keep your tablets in their original pack at a temperature below 30°C
- Keep medicines out of reach of children

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 to off white colored, oval shaped, biconvex, bevel edged, film coated tablets, debossed '10' on one side and breakline on other side.

Ingredients

- Active ingredient Memantine Hydrochloride, pulverized
- Inactive ingredients
 Cellulose microcrystalline (Avicel PH200)
 Crospovidone XL 10
 Colloidal Silicon Dioxide
 Talc
 Magnesium Stearate
 Hypromellose 2910 (6cps)
 Polyethylene Glycol 400
 Titanium dioxide
 Purified water

MAL number:

MAL

Manufacturer

Torrent Pharmaceuticals Ltd. Indrad 382 721, District: Mehsana India.

Product Registration Holder

Laboratories Torrent (Malaysia) Sdn Bhd.

Suite E-08-08 Plaza Mont Kiara No. 2 Jalan Kiara Mont Kiara 50480 Kuala Lumpur Malaysia.

Date of Revision

17/03/2015