

Package leaflet: Information for the user

Memantine 10 mg film-coated tablets
Memantine 20mg film-coated tablets

Memantine hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Memantine is and what it is used for
2. What you need to know before you take Memantine
3. How to take Memantine
4. Possible side effects
5. How to store Memantine
6. Contents of the pack and other information

1. What Memantine is and what it is used for

How does Memantine work

Memantine belongs to a group of medicines known as anti-dementia medicines. 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. Memantine belongs to a group of medicines called NMDA-receptor antagonists. Memantine acts on these NMDA-receptors improving the transmission of nerve signals and the memory.

What is Memantine used for

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

2. What you need to know before you take Memantine

Do not take Memantine

- if you are allergic to memantine hydrochloride or any of the other ingredients of this medicine (listed in section 6).

Warning and precautions

Talk to your doctor or pharmacist before taking Memantine:

- 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 Memantine reassessed 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.

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.

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 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.

Children and adolescents

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

Other medicines and Memantine

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

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

- amantadine, ketamine, 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 Memantine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

The use of memantine in pregnant women is not recommended.

Women taking Memantine should not breast-feed.

Driving and using machines

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

3. How to take Memantine

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Memantine can be taken with or without food.

Dosage

The recommended dose of Memantine for adults and elderly patients is 20 mg, 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	5 mg once a day
week 2	10 mg once a day
week 3	15 mg once a day
week 4 and beyond	20 mg once a day

The usual starting dose is 5 mg once a day for the first week. This is increased to 10 mg once a day in the second week and to 15 mg once a day in the third week. From the fourth week on, the usual dose is 20 mg once a day.

Maintenance dose

The recommended daily dose is 20 mg once a day.

For continuation of the treatment please consult your doctor.

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.

Method of administration

Memantine should be taken orally once a day. To benefit from your medicine you should take it **regularly every day at the same time of the day**. The tablets should be swallowed with some water.

The tablets can be taken with or without food.

Duration of treatment

Continue to take Memantine as long as it is of benefit to you. Do not stop taking the tablets unless told to do so by your doctor. If you stop taking this medicine, the benefits of your treatment will gradually fade away. Your doctor should assess your treatment on a regular basis.

If you take more Memantine than you should

- In general, taking too much Memantine should not result in any harm to you. You may experience increased symptoms as described in section 4. "Possible side effects".
- If you take a large overdose of Memantine, contact your doctor or get medical advice, as you may need medical attention.

If you forget to take Memantine

Do not take a double dose to make up for a forgotten dose. If you find you have forgotten to take your dose of Memantine, wait and take your next dose at the usual time.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

In general, the observed side effects are mild to moderate.

However, Alzheimer's disease in itself has been associated with depression, suicidal ideation and suicide. These events have been also reported in patients treated with Memantine. You must **tell your doctor immediately** if you notice that you are depressed or have thoughts about harming yourself.

Common side effects (may affect up to 1 in 10 people):

- Headache, sleepiness, constipation, elevated liver function tests, dizziness, balance disorders, shortness of breath, high blood pressure and drug hypersensitivity

Uncommon side effects (may affect up to 1 in 100 people):

- Tiredness, fungal infections, confusion, hallucinations, vomiting, abnormal gait, heart failure and venous blood clotting (thrombosis/thromboembolism)

Very Rare side effects (may affect up to 1 in 10,000 people):

- Seizures

Not known (frequency cannot be estimated from the available data):

- Inflammation of the pancreas, inflammation of the liver (hepatitis) and psychotic reactions

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. How to store Memantine

Keep this medicine out of the sight and reach of children.

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

Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Memantine contains

The active substance is memantine hydrochloride.

Each 10 mg film-coated tablet contains 10 mg of memantine hydrochloride equivalent to 8.31 mg memantine.

Each 20 mg film-coated tablet contains 20 mg of memantine hydrochloride equivalent to 16.62 mg memantine.

- The other ingredients are microcrystalline cellulose, crospovidone (Type B), colloidal anhydrous silica, talc, magnesium stearate, hypromellose, macrogol 400, titanium dioxide [E 171].

- Additional colorants in the 20 mg coating are ferric oxide yellow [E 172] and ferric oxide red [E 172]

What Memantine looks like and contents of the pack

Memantine 10 mg film-coated tablets are white to off-white colored, oval shaped, approx. 13.0 x 5.5 mm, biconvex, bevel edged, film coated tablets, debossed '10' on one side and score line on other side. The tablet can be divided into equal doses.

Memantine 20 mg film-coated tablets are pale red to grey red colored, oval shaped, approx. 15.3 x 6.2 mm, biconvex, bevel edged, film coated tablets, debossed '20' on one side and plain on other side.

Memantine film-coated tablets are available in blister packs of 28, 30, 42, 50, 56, 98 or 100 tablets.

Marketing Authorisation Holder and Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

DE	Memantin Heumann 10 mg Filmtabletten
	Memantin Heumann 20 mg Filmtabletten
EL	Memantin Torrent 10 mg επικαλυμμένα με λεπτό υμένιο δισκία
	Memantin Torrent 20 mg επικαλυμμένα με λεπτό υμένιο δισκία
LT	Memantinas Torrent 10 mg plėvele dengtos tabletės
	Memantinas Torrent 20 mg plėvele dengtos tabletės
RO	Memantina Torrent 10 mg comprimate filmate
	Memantina Torrent 20 mg comprimate filmate
UK	Memantine Torrent 10 mg Film-coated Tablets
	Memantine Torrent 20 mg Film-coated Tablets

This leaflet was last revised in 02/2013

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Colour Black

LOCATION : Indrad	COUNTRY : UK	Supersedes A/W No.:		
SIZE : 150 x 450 mm_Front/Back Side	CODE : 8039738-7803	DATE : 20-02-2013		
REMARK : Folding Length 35 mm				
SUBSTRATE :				
Activities	Department	Name	Signature	Date
Prepared By	Pkg.Dev			
Reviewed By	Pkg.Dev			
Reviewed By	RA			
Approved By	CQA			
This colour proof is not colour binding. Follow Pantone shade reference for actual colour matching.				



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