Package leaflet: Information for the user

Memantine Clonmel 10mg 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. See section 4.

What is in this leaflet

1. What Memantine Clonmel is and what it is used for

How does Memantine Clonmel work
Memantine Clonmel 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 Clonmel belongs to a group of medicines called NMDA-receptor antagonists. Memantine Clonmel acts on these NMDA-receptors improving the transmission of nerve signals and the memory.

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

2. What you need to know before you take Memantine Clonmel

Do not take Memantine Clonmel
- if you are allergic to memantine hydrochloride or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Memantine Clonmel
- 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 Clonmel 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.

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

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

In particular, Memantine Clonmel 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 Clonmel.

Memantine Clonmel with food and drink
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 tubulary 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.

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

Pregnancy
The use of memantine in pregnant women is not recommended.

Breast-feeding
Women taking Memantine Clonmel 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 Clonmel may change your reactivity, making driving or operating machinery inappropriate.

Memantine Clonmel contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Memantine Clonmel

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

Dosage
The recommended dose of Memantine Clonmel 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	half a 10 mg tablet
Week 2	one 10 mg tablet
Week 3	one and a half 10 mg tablet
Week 4 and beyond	two 10 mg tablets once a day

The usual starting dose is half a tablet once a day (1 × 5 mg) for the first week. This is increased to one tablet once a day (1 × 10 mg) in the second week and to 1 and a half tablet once a day in the third week. From the fourth week on, the usual dose is 2 tablets once a day (1 × 20 mg).

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
Memantine Clonmel 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. The tablets should be swallowed with some water.
The tablets can be taken with or without food.

Duration of treatment
Continue to take Memantine Clonmel as long as it is of benefit to you. Your doctor should assess your treatment on a regular basis.

If you take more Memantine Clonmel than you should
- In general, taking too much Memantine Clonmel 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 Clonmel, contact your doctor or get medical advice, as you may need medical attention.

If you forget to take Memantine Clonmel
- If you find you have forgotten to take your dose of Memantine Clonmel, 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 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.

Common (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 (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 (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

Alzheimer's disease has been associated with depression, suicidal ideation and suicide. These events have been reported in patients treated with memantine.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: For Ireland: HPRA Pharmacovigilance Website www.hpra.ie For Malta: ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Memantine Clonmel

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.

This medicinal product does not require any special storage conditions.

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 protect the environment.

6. Contents of the pack and other information

What Memantine Clonmel contains
- The active substance is memantine hydrochloride. Each film-coated tablet contains 10 mg memantine hydrochloride equivalent to 8.31 mg memantine.

- The other ingredients are microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica and magnesium stearate, all in the tablet core; and polyvinyl alcohol, titanium dioxide (E171), macrogol (3350) and talc, all in the tablet coating.

What Memantine Clonmel looks like and contents of the pack
Memantine Clonmel film-coated tablets are presented as white, slim through the middle, biconvex, 10 mm – 5.6 mm, film-coated tablet with breaking lines on both sides and engraving '10' on one side.

The tablet can be divided into equal doses.

Blister packs containing either 7, 10, 14, 15 or 20 tablets per blister (PVC/PE/PVDC and Aluminium).
Memantine Clonmel film-coated tablets are presented in pack sizes of 7, 14, 28, 30, 42, 50, 56, 60, 98, 110, 112, 168 or 180 film-coated tablets.
Blister packs containing either 7 x 1, 10 x 1, 14 x 1, 15 x 1 or 20 x 1 tablets per blister (unit dose PVC/PE/PVDC and Aluminium).
Memantine Clonmel film-coated tablets are presented in pack sizes of 7, 14, 28, 30, 42, 50, 56, 60, 98, 110, 112, 168 or 180 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Clonmel Healthcare Ltd,Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer
STADA Arzneimittel AG, Stadastrasse 2–18, 61118 Bad Vilbel, Germany
Clonmel Healthcare Ltd,Waterford Road, Clonmel, Co. Tipperary, Ireland

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

AT:	Memantin STADA 10 mg Filmtabletten
BE:	Memantine EG 10mg filmomhulde tabletten
BG:	Memantine STADA 10 mg film-coated tablets
CZ:	MEMANTIN STADA 10mg potahované tablety
DE:	Memantinhydrochlorid STADA 10 mg Filmtabletten
ES:	Memantina STADA 10 mg comprimdos recubiertos con película EFG
FR:	MEMANTINE EG 10 mg, comprimé pelliculé
HU:	Memantin Stada 10 mg filmtabletta
IE:	Memantine Clonmel 10 mg film-coated tablets
LU:	Memantine EG 10mg comprimés pelliculés
MT:	Memantine Clonmel 10 mg film-coated tablets
NL:	Memantine HCl CF 10 mg, filmomhulde tabletten
PT:	Memantina Ciclum 10 mg
SK:	Memantin Stada filmom obalené tablety10 mg

This leaflet was last revised in February 2021.