

Package leaflet: Information for the user

Memantine Clonmel 10mg/ml Oral Solution

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 side effects not listed in this leaflet.

What is in this leaflet:

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

1. WHAT MEMANTINE CLONMEL IS AND WHAT IT IS USED FOR

Memantine Clonmel contains the active substance memantine hydrochloride.

What is Memantine Clonmel used for

Memantine Clonmel is used to treat patients with moderate to severe Alzheimer's disease in adults.

How Memantine Clonmel works

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.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MEMANTINE CLONMEL

Do not take Memantine Clonmel if you are allergic (hypersensitive) to memantine hydrochloride or any of the other ingredients of this medicine. (See 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 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, drink and alcohol

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.

Pregnancy, breast-feeding and fertility

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

The use of memantine in pregnant women is not recommended.

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 Sorbitol

This medicine contains 100 mg sorbitol in each ml of oral solution. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

3. HOW TO TAKE MEMANTINE CLONMEL

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

Dosage

(a) Pump pack of 5mg/pump actuation:

One pump actuation contains 5 mg memantine hydrochloride.

The recommended dose of Memantine Clonmel for adults and elderly patients is four pump actuations, equivalent to 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 | One downward pump (equivalent to 0.5 ml) |
| week 2 | Two downward pumps (equivalent to 1 ml) |
| week 3 | Three downward pumps (equivalent to 1.5 ml) |
| week 4 and beyond | Four downward pumps (equivalent to 2 ml) |

The usual starting dose is one pump actuation once daily (1 x 5 mg) for the first week. This dose is increased in the second week to two pump actuations once daily (1 x 10 mg), and in the third week to three pump actuations once daily (1 x 15 mg). From the fourth week the recommended dose is four pump actuations once daily (1 x 20 mg).

(b) Dosing Pipette:

| | |
|-------------------|--------|
| week 1 | 0.5 ml |
| week 2 | 1 ml |
| week 3 | 1.5 ml |
| week 4 and beyond | 2 ml |

The usual starting dose is 0.5 ml once daily (1 x 5 mg) for the first week. This dose is increased in the second week to 1 ml once daily (1 x 10 mg), and in the third week to 1.5 ml once daily (1 x 15 mg). From the fourth week the recommended dose is 2 ml once daily (1 x 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 solution should be taken with a little water. The solution can be taken with or without food.

For detailed instructions on the preparation and handling of the product see end of this leaflet.

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 stop taking Memantine Clonmel

If you want to stop the treatment before finishing the course of treatment discuss with your doctor or pharmacist first.

If you have any further questions on the use of this product, 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 (affects 1 to 10 users in 100):

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

Uncommon (affects 1 to 10 users in 1,000):

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

Very rare (affects less than 1 user in 10,000):

- 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 Clonmel.

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

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 bottle label after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Once opened, the contents of the bottle should be used within 12 weeks.

If using the bottle with the mounted pump the bottle must be kept and transported in an upright position only.

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.
Pump: Each pump actuation (one downward pump) delivers 0.5 ml of solution containing 5 mg of memantine hydrochloride equivalent to 4.16 mg memantine.
Dosing Pipette: 0.5 ml contains 5 mg of memantine hydrochloride equivalent to 4.16 mg of memantine.

Each ml of solution contains 10 mg of memantine hydrochloride.

- The other ingredients are potassium sorbate E202, sorbitol E420 and purified water.

What Memantine Clonmel looks like and contents of the pack

Memantine Clonmel oral solution is presented as a clear, colourless to light yellowish solution. Memantine Clonmel oral solution is available in bottles of 50 ml, 100 ml or 10 x 50 ml. A pump or dosing pipette is provided. The dosing pipette is printed in 0.5 ml graduations. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer:

Chanelle Medical, Loughrea, Co. Galway, Ireland

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:

| | |
|------------------|---|
| The Netherlands: | Memantine CF 10 mg/ml, drank |
| Spain: | Memantina Stada 5 mg/pulsación, solución oral EFG |
| Ireland: | Memantine Clonmel 10 mg/ml oral solution |
| Malta: | Memantine Clonmel 10 mg/ml oral solution |
| Portugal: | Memantina Ciclum |

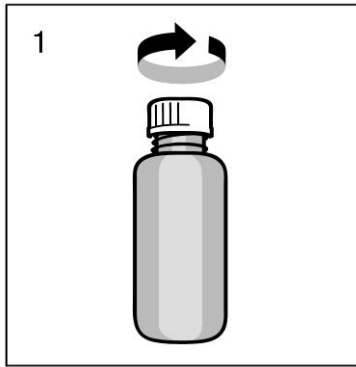
This leaflet was last revised in August 2020.

Instruction for proper use of the pump

The solution must not be poured or pumped directly into the mouth from the bottle or pump. Measure the dose onto a spoon or into a glass of water, using the pump.

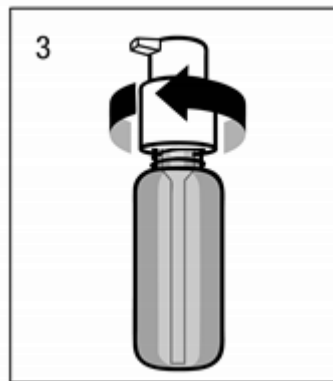
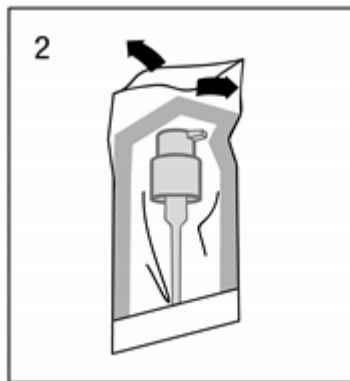
Take the screw cap off the bottle:

The cap must be turned anticlockwise, unscrewed completely and removed (fig 1).



Mounting the dosing pump on the bottle:

Take the dosing pump out of the plastic bag (fig 2) and place it on top of the bottle. Slide the plastic dip tube carefully into the bottle. Hold the dosing pump onto the neck of the bottle and screw it clockwise until it fits firmly (fig 3). The dosing pump is only screwed on once when starting the use, and should never be unscrewed.



How the dosing pump works:

The dosing pump head has two positions and is easy to turn:

- anticlockwise to unlock and
- clockwise to lock.

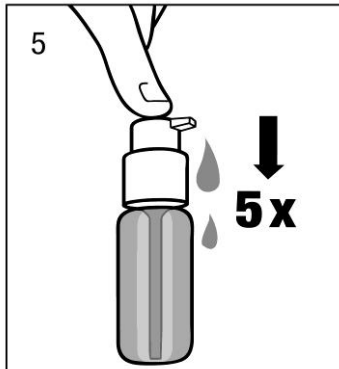
The dosing pump head should not be pushed down while in the locked position. The solution may only be dispensed in the unlocked position. To unlock, turn the pump head in the direction of the arrow until it cannot be turned any further (about one eighth of a turn, fig 4).

The dosing pump is then ready for use.



Preparing the dosing pump:

When used for the first time, the dosing pump does not dispense the correct amount of oral solution. Therefore, the pump must be prepared (primed) by pushing the dosing pump heads down completely five times in succession (fig 5).

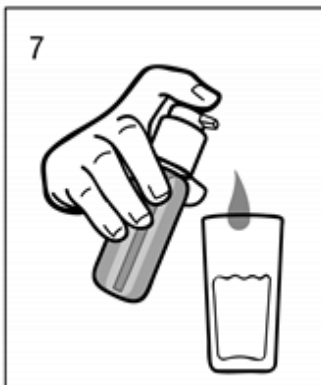


The solution thus dispensed is discarded. The next time the dosing pump head is pushed downwards completely (equivalent to one pump actuation), it dispenses the correct dose (fig 6).



Correct use of the dosing pump:

Hold a glass with a little water or a spoon below the nozzle. Push down the dosing pump head in a firm but calm and steady manner - not too slowly (fig 7, fig 8).

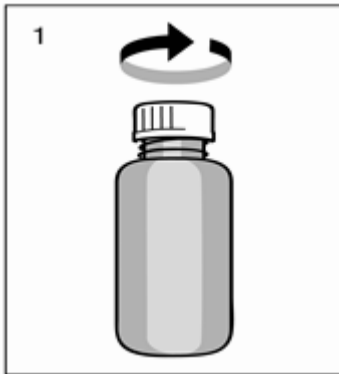




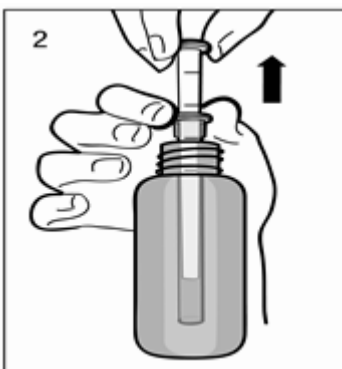
The dosing pump head can then be released and is ready for the next pump compression. The dosing pump must only be used with the Memantine Clonmel solution in the bottle provided, not for other substances or containers. If the pump does not function properly, consult your doctor or pharmacist. Lock the dosing pump after using Memantine Clonmel.

Instruction for proper use of the dosing pipette

Remove the cap from the bottle by turning it anti-clockwise (fig 1).



Insert the pipette into the bottle. While holding the bottom ring, pull the top ring up to the mark that corresponds to the number of millilitres or milligrams you need to give (fig 2).



Holding the bottom ring, remove the entire pipette from the bottle. The solution must not be pipetted into the mouth directly from the bottle but should be dosed onto a spoon or into a glass of water using the pipette (fig 3).

