



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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

Ireland
IMB Pharmacovigilance,
Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971 Fax: +353 1 6762517
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie

5. How to store Memantine Oral Solution

- Keep out of the sight and reach of children.
Do not use Memantine Oral Solution 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.
Do not store above 30°C.
Once opened, the contents of the bottle should be used within 3 months.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Memantine Oral Solution contains

- The active substance is memantine hydrochloride. Each ml of solution contains 10mg of memantine hydrochloride which is equivalent to 8.32mg memantine.
The other ingredients are potassium sorbate, sorbitol solution (non crystallising) (E420) and purified water.

What Memantine Oral Solution looks like and contents of the pack

Memantine Oral Solution is presented as a clear, colourless solution. Memantine Oral Solution is available in bottles of 50ml or 100ml with an oral dosing syringe and bottle adaptor.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.
Tel: + 44 (0) 113 244 1400

This leaflet was last revised in 06/2014.

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

- Memantine Hydrochloride 10mg/ml Oral Solution: UK/Eire
Mémantine Rosemont 10mg/ml Solution Buvable: France
Memantin Rosemont 10mg/ml Lösung zum Einnehmen: Germany

Other sources of information

This leaflet is also available in other formats for blind and partially-sighted patients. For large print and Braille, please go to UK: www.xpil.medicines.org.uk Ireland: www.medicines.ie
For an audio version, please go to www.rosemontpharma.com/products

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

1. What Memantine Oral Solution is and what it is used for

How does Memantine Oral Solution work

Memantine Oral Solution 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 Oral Solution used for

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

2. What you need to know before you take Memantine Oral Solution

Do not take Memantine Oral Solution

- if you are allergic (hypersensitive) to the memantine hydrochloride or any of the other ingredients of Memantine Oral Solution (see section 6).

Warnings and precautions

Talk to your doctor before taking Memantine Oral Solution:

- 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 Oral Solution reassessed by your doctor on a regular basis.

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.

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

Other medicines and Memantine

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, 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.

Continued overleaf

Form containing product details, dates, and regulatory sign-off sections.

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If you go into hospital, let your doctor know that you are taking Memantine Oral Solution.

Pregnancy, breast-feeding and fertility

Ask your doctor or pharmacist for advice 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 Memantine Oral Solution 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 Oral Solution may change your reactivity, making driving or operating machinery inappropriate.

Memantine Oral Solution contains sorbitol and potassium.

This medicine contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. Your doctor will advise you on what you should do.

Furthermore, this medicine contains potassium, less than 1mmol (39mg) per dose, i.e. essentially potassium free.

3. How to take Memantine Oral Solution

Always take Memantine Oral Solution exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

Each millilitre (ml) of Memantine Oral Solution contains 10 milligrams (mg) memantine hydrochloride.

The recommended dose of Memantine Oral Solution for adults and elderly patients is 20mg (2ml) once a day.

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

Week	Dose to take
Week 1	5mg (0.5ml)
Week 2	10mg (1ml)
Week 3	15mg (1.5ml)
Week 4 and beyond	20mg (2ml)

- The usual starting dose is 0.5ml once daily for the first week.
- This dose is increased in the second week to 1ml once daily.
- This dose is increased in the third week to 1.5ml once daily.
- From the fourth week the recommended dose is 2ml once daily.

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.

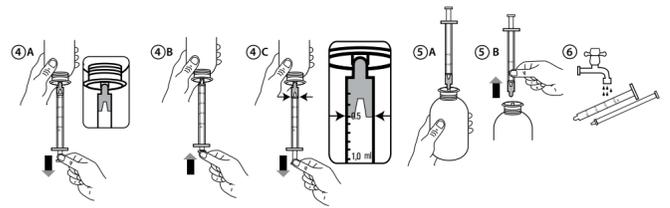
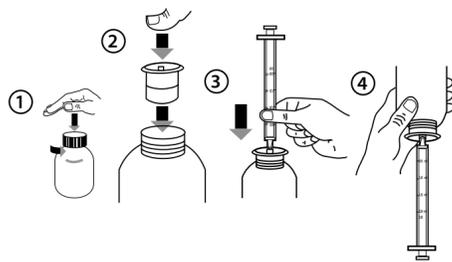
Administration

- Memantine Oral Solution 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 may be taken with a little water.
- The solution can be taken with or without food.

Measuring your dose

Instructions for use

- Open the bottle: press the cap and turn it anticlockwise (Figure 1).
- Insert the syringe adaptor into the bottle neck (Figure 2).
- Take the syringe and put it in the adaptor opening (Figure 3).
- Turn the bottle upside down (Figure 4).



- Fill the syringe with a small amount of solution by pulling the piston down (Figure 4A). Then push the piston upward in order to remove any possible bubbles (Figure 4B). Finally, pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor. The top flat edge of the piston should be in line with the graduation mark you are measuring to (Figure 4C).
- Turn the bottle the right way up (Figure 5A).
- Remove the syringe from the adaptor (Figure 5B).
- Put the end of the syringe into your mouth and push the piston slowly back in to take the medicine. Alternatively, dispense the solution onto a spoon or into a small glass of water and take your medicine straight away.
- Wash the syringe with water and let it dry before you use it again (Figure 6).
- Close the bottle with the plastic screw cap - leave the syringe adaptor in the bottle.

Duration of treatment

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

If you take more Memantine Oral Solution than you should

- In general, taking too much Memantine Oral Solution 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 Oral Solution, contact your doctor or get medical advice, as you may need medical attention.

If you forget to take Memantine Oral Solution

- If you find you have forgotten to take your dose of Memantine Oral Solution, 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, Memantine Oral Solution can cause side effects, although not everybody gets them. If any of the following side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 (shown in blood tests)
- dizziness, balance disorders
- shortness of breath
- high blood pressure
- drug hypersensitivity.

Uncommon: affects 1 to 10 users in 1,000

- tiredness
- fungal infections
- confusion, hallucinations
- vomiting
- abnormal gait
- heart failure
- 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)
- psychotic reactions.

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

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.

Continued overleaf

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Rosemont Pharmaceuticals Ltd. Printed Packaging Origination and Approval			Third Party Approval Required YES <input type="checkbox"/> NO <input type="checkbox"/> <small>Tick applicable box</small>	
Product:	Memantine Hydrochloride 10mg/ml Oral Solution	Date:	16.06.14	
Strength:	10mg/ml	Proof Number:	ELEVEN	
New Item Code:	POXXX	Page:	2 of 2	
Previous Item Code:	-	New Pharmacode:		
Design Icon:	Rosemont	Sugar-Free	YES	
Cutter Ref:	-	Pack Size	50ml 100ml	
Dimensions:	30 x 300mm (folded 150 x 37mm)			
Number of colours used:	ONE	Black	Keyline	
			Name: _____	
			Signature: _____ Date: ___/___/___	
Regulatory Sign-off				
			Name: _____	
			Signature: _____ Date: ___/___/___	

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