Memantine Hydrochloride 10mg/ml Oral Solution

1. What Memantine is and what it is used for

Memantine contains the active substance memantine hydrochloride.

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

2. What you need to know before you take Memantine

Dosage

Always take Memantine exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist what the recommended dose for you is. The recommended dose of Memantine for adults and elderly patients is four pump actuations, equivalent to 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 0: One pump actuation (equivalent to 0.5mg).
Week 1: Two pump actuations (equivalent to 1.0mg).
Week 2: Three pump actuations (equivalent to 1.5mg).
Week 3: Four pump actuations (equivalent to 2.0mg).

The usual starting dose is one pump actuation every day (0.5mg) for the first week. This dose is increased in increments of one actuation (0.5mg) each week (total dose 6.5mg) until the fourth week when the recommended dose is reached (10mg once a day).

Dosage in patients with impaired kidney function

If you have reduced 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 should be administered orally once a day. To benefit from this medication you should take it regularly every day at the same time of the day.

Advice on missed doses

If you forget to take a dose, take it as soon as you remember (even if it is near the next dose). If you do, however, miss two doses in a row you should contact your doctor. Do not take a double dose to make up for a forgotten dose.

Serious side effects

In these situations the treatment should be carefully supervised, and the clinical benefit of Memantine reassessed.

3. How to take Memantine

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

SwallowingMEMANTINE should be swallowed whole, with or without food. The solution should be taken with a little water. The solution can be taken with food, drink and alcohol.

4. Possible side effects

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

Other medicines and Memantine

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

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

· If you have any further questions, ask your doctor or pharmacist.

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Memantine Oral Solution 10mg/ml PIL - UK

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4. Possible side effects

Like all medicines, this medicinal product can cause side effects, although not everybody gets them. In general, the side effects of Memantine are mild to moderate. However, the following side effects have been reported in patients treated with Memantine:

- GI tract disorders (affects 1 to 10 users in 100):
- Nausea
- Vomiting
- Diarrhoea
- Rectal bleeding

- Immune system disorders (affects 1 to 10 users in 100):
- Anaphylaxis
- Allergic reactions
- Urticaria
- Contact urticaria

- Mental and behavioural disorders (affects 1 to 10 users in 100):
- Depression
- Agitation
- Anxiety

- Nervous system disorders (affects 1 to 10 users in 100):
- Dizziness
- Seizures
- Drowsiness

- Skin and subcutaneous tissue disorders (affects 1 to 10 users in 100):
- Rash
- Urticaria
- Exfoliative dermatitis

- Blood and lymphatic system disorders (affects 1 to 10 users in 100):
- Anaemia
- Decreased platelet counts

- Musculoskeletal and connective tissue disorders (affects 1 to 10 users in 100):
- Myalgia
- Arthralgia

- Reproductive system and breast disorders (affects 1 to 10 users in 100):
- Amenorrhoea

- Nutritional and metabolic disorders (affects 1 to 10 users in 100):
- Diabetes mellitus

- Urogenital and reproductive system disorders (affects 1 to 10 users in 100):
- Dysuria
- Reduced libido
- Sexual dysfunction

- Respiratory, thoracic and mediastinal disorders (affects 1 to 10 users in 100):
- Asthma
- Pneumonia

- Cardiac disorders (affects 1 to 10 users in 100):
- Palpitations

- Vascular disorders (affects 1 to 10 users in 100):
- Venous thrombosis

- Injection site conditions (affects 1 to 10 users in 100):
- Injection site reactions

- General disorders and administration site conditions (affects 1 to 10 users in 100):
- Malaise
- Fatigue

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

4.2. Overdose

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 still feel unwell, contact your doctor or pharmacist immediately. If you think that you or anybody else may have taken an overdose of this medicinal product, you should contact a hospital or poison centre straight away.

4.3. What happens if you take Memantine after the expiry date

Medicines can become less effective if there is an extended time between the manufacture date and the expiry date. This leaflet was last revised in July 2017.

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 bottle label after EXP.
- The medicinal product does not require any special storage conditions.

6. Contents of the pack and other information

6.1. What Memantine 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 hydrochloride.
- Memantine solution: Each vial contains 40 mg of memantine hydrochloride equivalent to 4.16 mg memantine hydrochloride. The other ingredients are polysorbate 20, sodium hydroxide and purified water.

6.2. What Memantine looks like and contains of the pack

Memantine solution is presented as a clear, colourless to light yellowish solution. Memantine oral solution is available in bottles of 50 ml and 100 ml. A pump is provided.

6.3. Marketing Authorisation Holder

Accord Healthcare Limited
Sage House, 11 Honeywood Road, North Mankin, Wakefield, West Yorks, WF1 4EF, United Kingdom

6.4. Manufacturer

Chanelle Medical
Loughrea, Co. Galway, Ireland.

6.5. Date of adoption and review

This leaflet was last revised in July 2017.

6.6. How the dosing pump works

The dosing pump head has two positions and a way to turn it clockwise or anticlockwise. The dosing pump head should not be pushed down while in the locked position. The solution must not be poured or pumped directly into the mouth from the bottle or pump.

- Take the screw cap off the bottle:
- Mounting the dosing pump on the bottle:
- How to store Memantine:

- 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 head downwards five times in succession (fig 5.)
- Preparing the dosing pump:

- The dosing pump head has two positions and is easy to turn:
- The cap must be turned anticlockwise, unscrewed completely and removed (fig 1).
- The cap must be turned clockwise, screwed on and locked (fig 3).
- The dosing pump head should not be pushed down while in the locked position. Therefore, the pump must be prepared (primed) by pushing the dosing pump head downwards five times in succession (fig 5.)
- 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. 2). The dosing pump is only approved for use with the Memantine solution in the bottle.
- When used for the first time, the dosing pump does not dispense the correct amount of oral solution.