PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Memantine Teva 10 mg Film-coated Tablets
Memantine Teva 20 mg 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 Teva is and what it is used for

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

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

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

Do not take Memantine Teva
- 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 Teva:
- 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 Teva 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.

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.

The use of medicines 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 Teva is not recommended for children and adolescents under the age of 18 years.

Other medicines and Memantine Teva
Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

In particular, Memantine Teva 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 Teva.

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.

The use of memantine in pregnant women is not recommended.

Women taking Memantine Teva 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 Teva may change your reactivity, making driving or operating machinery inappropriate.

3. How to take Memantine Teva

<u>Memantine Teva 10 mg Film-coated Tablets</u>:
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 Teva 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 tablets
week 4 and beyond	two 10 mg tablets once a day

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

The tablet can be divided into equal doses.

<u>Memantine Teva 20 mg Film-coated Tablets</u>:
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 Teva 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. For up-titration other tablet strengths are available.

At the beginning of treatment you will start by using 5 mg once a day. This dose will be increased weekly by 5 mg until the recommended (maintenance) dose is reached. The recommended maintenance dose is 20 mg once a day, which is reached at the beginning of the 4th week.

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

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

If you forget to take Memantine Teva
- If you find you have forgotten to take your dose of Memantine Teva, 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, shortness of breath, balance disorders, 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Memantine Teva

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, the bottle and the blister pack after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

[HDPE bottles- 30 tablets]:
Memantine Teva should be used no longer than 30 days after first opening of the bottle.

[HDPE bottles- 100 tablets]:
Memantine Teva should be used no longer than 100 days after first opening of the bottle.

[HDPE bottles- 200 tablets]:
Memantine Teva should be used no longer than 200 days after first opening of the bottle.

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 Teva contains
The active substance is memantine hydrochloride.
Each 10 mg film-coated tablet contains 10 mg memantine hydrochloride equivalent to 8.31 mg memantine.
Each 20 mg film-coated tablet contains 20 mg memantine hydrochloride equivalent to 16.62 mg memantine.

Memantine Teva 10 mg Film-coated Tablets:
The other ingredients are microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica and magnesium stearate, all in the tablet core; and hypromellose, titanium dioxide (E171) and talc, all in the tablet coating.

Memantine Teva 20 mg Film-coated Tablets:
The other ingredients are microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate, all in the tablet core; and hypromellose, macrogol 6000, macrogol 400, titanium dioxide (E 171), iron oxide red (E 172), indigotine (E 132) and iron oxide black (E172), all in the tablet coating.

What Memantine Teva looks like and contents of the pack

Memantine Teva 10 mg Film-coated Tablets are presented as white to off white, oval shaped film coated tablets, approximately 9.1 mm x 4.6 mm. On one side debossed with "M" on either side of the score, and on the other side with "1" on the left side of the score and with “0” on the right. The tablet can be divided into equal doses.

Memantine Teva 10 mg Film-coated Tablets are available in blister packs of 14, 14x1, 20, 20x1, 21, 21x1, 28, 28x1, 30, 30x1, 42, 42x1, 50, 50x1, 50x1 (hospital pack), 56, 56x1, 60, 60x1, 90, 90x1, 98, 98x1, 100, 100x1, 112, 112x1, 120, 120x1, 168, 168x1, 180, 180x1 film-coated tablets or bottles with 30, 100 and 200 film-coated tablets.

Not all pack sizes may be marketed.

Memantine Teva 20 mg Film-coated Tablets are presented as light pink to pink, oval shaped film coated tablets, approximately 12.1 mm x 6.5 mm, debossed with "M" on one side of the tablet and with "20" on the other side.

Memantine Teva 20 mg Film-coated Tablets are available in blister packs of 14, 14x1, 20, 20x1, 21, 21x1, 28, 28x1, 28 (calendar pack), 28x1 (calendar pack), 30, 30x1, 42, 42x1, 50, 50x1, 50x1 (hospital pack), 56, 56x1, 56 (calendar pack), 56x1 (calendar pack), 60, 60x1, 90, 90x1, 98, 98x1, 100, 100x1, 112, 112x1, 120, 120x1, 168, 168x1, 180, 180x1 film-coated tablets or bottles with 30, 100 and 200 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Teva Pharma B.V.,
Swensweg 5
2031GA Haarlem, The Netherlands

Manufacturer(s):
TEVA Pharmaceutical Works Private Limited Company, Pallagi út 13, 4042 Debrecen, Hungary

Teva Operations Poland Sp. z.o.o., ul. Mogilska 80., 31-546, Krakow, Poland

TEVA UK Ltd, Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG, United Kingdom

Pharmachemie B.V., Swensweg 5, 2031 GA Haarlem, The Netherlands

TEVA PHARMA S.L.U., C/C, n. 4, Poligono Industrial Malpica, 50016 Zaragoza, Spain
Merckle GmbH, Ludwig-Merckle-Straße 3, 89143 Blaubeuren, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:
Germany Memantin AbZ
Denmark Memantine Teva
Greece Memantine Teva
Spain MEMANTINA TEVA EFG
France Mémantine Teva
Italy Memantina Teva
Malta Memantine Teva
Netherlands Memantine Teva
Poland Memantine Teva
Slovenia Memantin Teva
United Kingdom Memantine Hydrochloride
Belgium Memantine Teva
Hungary Memantin-Teva

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