PATIENT INFORMATION LEAFLET

Memora10 mg Film-Coated Tablets
Memora 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. Do not pass it on to others. It may harm them, even if their sign 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 Memora is and what it is used for

Memora contains the active substance memantine hydrochloride. It 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. Memora belongs to a group of medicines called NMDA-receptor antagonists. Memora acts on these NMDA-receptors improving the transmission of nerve signals and the memory.

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

2. What you need to know before you take Memora

Do not take Memora:
- If you are allergic to memantine hydrochloride or any of the other ingredients of Memora film-coated tablets (see section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Memora, if you:
- Have a history of epileptic seizures
- 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 Memora 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.
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), your doctor may need to adjust the dose of your medicine.

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

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

Other medicines and Memora

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines.
In particular, Memora 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 Memora.

Memora 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) 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 Memora 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, Memora may change your reactivity, making driving or operating machinery inappropriate.

3. How to take Memora

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

Taking this medicine
- Memora should be administered orally once a day.
- The tablets should be swallowed with some water.
- To benefit from your medicine you should take it regularly every day at the same time of the day.
- The tablets can be taken with or without food.

The recommended dose of Memora 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 or one 20 mg tablet once a day

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

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.

Duration of treatment

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

If you take more Memora than you should

In general, taking too much Memora 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 Memora, contact your doctor or get medical advice, as you may need medical attention.

If you forget to take Memora

If you find you have forgotten to take your dose of Memora, 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, Memora can cause side effects, although not everybody gets them.
In general, the observed side effects are mild to moderate.
Common side effects (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 side effects (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 side effects (affects less than 1 user in 10,000): seizures.
Not known side effects (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 hydrochloride.

Reporting 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Memora
- 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 blister and the outer packaging. The expiry date refers to the last day of that month.
- Do not store above 30°C. Keep away from humidity.
- Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. 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 Memora Contains
- The active substance is memantine hydrochloride.
- Each film-coated tablet contains 10 mg or 20 mg memantine hydrochloride equivalent to 8.31 mg memantine or 16.62 mg memantine respectively.
- The other ingredients are:
  Tablet core: silicified microcrystalline cellulose , croscarmellose sodium, magnesium stearate.
  Tablet coating: polyvinyl alcohol, titanium dioxide, talc, lecithin, xantan gum.
  The 10 mg tablet includes iron oxide yellow.
  The 20 mg tablet includes iron oxide yellow and red.

What Memora looks like and contents of the pack

Memora 10 mg film-coated tablets are presented as yellow, round, film-coated tablets scored into two on one side.
Memora 20 mg film-coated tablets are presented as pink, round, film-coated tablets scored into two on one side.
Memora 10 mg and Memora 20 mg film-coated tablets are available in blister packs of 30 tablets.

Marketing Authorisation Holder and Manufacturer

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Reg. N° Lebanon for Memora 10 mg 138614/1
Reg. N° Lebanon for Memora 20 mg 138514/1

This is a medicament
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

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