PACKAGE LEAFLET

Package leaflet: Information for the user
MORYSA 10 mg Film-coated Tablets
MORYSA 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. See Section 4.

What is in this leaflet

1. What MORYSA is and what it is used for

MORYSA 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 N-methyl-D-aspartate (NMDA)-receptors that are involved in transmitting nerve signals important in learning and memory. MORYSA belongs to a group of medicines called NMDA-receptor antagonists. MORYSA acts on these NMDA-receptors improving the transmission of nerve signals and the memory.

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

You must talk to a doctor if you do not feel better or if you feel worse

2. What you need to know before you take MORYSA

Do not take MORYSA:

- 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 MORYSA
- if you have a history of seizures or epilepsy

- if you have recently experienced a heart attack (myocardial infarction), or if you are suffering from congestive heart failure (a type of heart disease where the heart cannot pump enough blood around the body) or from an uncontrolled high blood pressure (hypertension)

- if you are suffering from an excess of acid-forming substances in the blood due to poor kidney function (RTA; renal tubulary acidosis) or severe infections of the urinary system, as your doctor may need to adjust the dose of your medicine

- if you are on medication to treat Parkinson's disease (see - Other medicines and MORYSA).

In these situations your treatment should be carefully supervised, and the clinical benefit of MORYSA reassessed by your doctor on a regular basis.

If you have renal impairment (kidney problems), your doctor should closely monitor your kidney function and if necessary adapt the memantine hydrochloride doses accordingly.

Memantine hydrochloride is not recommended in people with severe liver impairment.

The use of medicinal products called amantadine (used in Parkinson's disease), ketamine (used as an anaesthetic), dextromethorphan (used to treat cough) and other NMDA-antagonists at the same time should be avoided.

Children and adolescents

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

Other medicines and MORYSA

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

MORYSA may change the effects of other medicines and their dose may need to be adjusted by your doctor.
Especially tell your doctor if you are taking medicines used to:

- treat Parkinson's disease (amantadine, L-dopa, bromocriptine (dopaminergic agonists))
- induce anaesthesia (ketamine)
- treat cough (dextromethorphan)
- reduce acid in the stomach (cimetidine, ranitidine)
- treat irregular heartbeat (procainamide,quinidine)
- prevent or treat malaria (quinine)
- help people stop smoking (smoking cessation; nicotine)
- make you urinate (diuretic such as hydrochlorothiazide or any combination with hydrochlorothiazide)
- treat movement disorders, muscle tightness (spasticity) or intestinal cramps (antispasmotic agents; dantrolene, baclofen, anticholinergics)
- prevent and relieve seizures (anticonvulsants; phenytoin)
- induce sleep (barbiturates)
- treat mental disorders (neuroleptics)
- thin the blood (oral anticoagulants)

If you go into hospital, let your doctor know that you are taking MORYSA.

MORYSA 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), 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 monitor you.

Pregnancy,breast-feeding and fertility

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 hydrochloride in pregnant women is not recommended.

Women taking MORYSA should not breast-feed.

Driving and using machines

MORYSA may change your reactivity, making driving or operating machinery inappropriate. Your doctor will tell you whether your illness allows you to drive and to use machines safely.

3. How to take MORYSA

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

Dosage

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

The usual starting dose is half a tablet once a day (5 mg) for the first week. The tablet can be divided into equal doses. This is increased to 1 tablet once a day (10 mg) in the second week and to 1 and a half tablets once a day (15 mg) in the third week. From the fourth week on, the usual dose is 2 tablets once a day (20 mg) or one 20 mg tablet 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.

Administration

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

If you take more MORYSA than you should

If you take more MORYSA than you should, tell your doctor or go to hospital straight away. Take the medicine pack with you. You may experience increased symptoms as described in section 4. "Possible side effects" and medical treatment may be required.

If you forget to take MORYSA

If you have forgotten to take your dose of MORYSA, 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 (affects 1 to 10 users in 100):

- allergic reaction (drug hypersensitivity)
- headache
- sleepiness (somnolence)
- constipation
- elevated liver function tests
- dizziness
- altered balance (balance disorders)
- shortness of breath(dyspnoea)
- high blood pressure (hypertension).

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

- tiredness (fatigue)
- fungal infections
- confusion
- hearing, seeing, feeling, smelling and even tasting things that are not real (hallucinations)
- being sick (vomiting)
- altered walk (abnormal gait)
- heart disease where the heart cannot pump enough blood around the body (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 (pancreatitis)
- inflammation of the liver (hepatitis)
- a break with reality (psychotic reactions).

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

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 listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store MORYSA

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

This medicine does not require any special storage conditions.

HDPE bottle: Do not use for more than 75 days after you first open it.

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

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

The other ingredients are:
Core Tablet: Cellulose microcrystalline, silica, colloidal anhydrous, croscarmellose sodium, hypromellose 2910, purified talc and magnesium stearate.
Tablet coat for 10 mg tablets: Instacoat Universal White (hypromellose 2910, macrogol 400, titanium dioxide (E171)).
Tablet coat for 20 mg tablets: Instacoat Universal Brown (hypromellose 2910, macrogol 400, titanium dioxide (E171), iron oxide yellow (E172) and iron oxide red (E172)).

What MORYSA looks like and contents of the pack

10 mg: MORYSA are presented as white to off-white, caplet shaped, biconvex film-coated tablets with a break line on both sides.

20 mg: MORYSA are presented as brown, oblong shaped, biconvex, film-coated tablets with break line on both sides.

MORYSA is available in blisters pack sizes of 28, 42, 56 and 98 tablets.

HDPE bottles with a white cap, aluminium seal and silica gel packet are available in pack sizes of 30, 100 and 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
To be completed nationally

Manufacturer
To be completed nationally

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

Czech Republic:	MORYSA 10 mg/ 20 mg Potahované tablety
Hungary:	MORYSA 10 mg/ 20 mg Filmtabletta
Poland:	MORYSA 10 mg/ 20 mg Tabletka powlekana
Portugal:	MORYSA 10 mg/ 20 mg Comprimido revestido por película
Slovakia:	MORYSA 10 mg/ 20 mg Filmom obalené tablety

This leaflet was last revised in {MM/YYYY}.