Package leaflet: Information for the patient

Xapimant 10 mg, filmomhulde tabletten
Xapimant 20 mg, filmomhulde tabletten
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 [Nationally completed name] is and what it is used for

How does [nationally completed name] work

[Nationally completed name] 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. [Nationally completed name] belongs to a group of medicines called NMDA-receptor antagonists. [Nationally completed name] acts on these NMDA-receptors improving the transmission of nerve signals and the memory.

What is [nationally completed name] used for

[Nationally completed] name is used for the treatment of patients with moderate to severe Alzheimer's disease.

2. What you need to know before you take [nationally completed name]

Do not take [nationally completed name]

- 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 [nationally completed name]:
- 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 [nationally completed name] 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.

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

[Nationally completed name] is not recommended for children and adolescents under the age of 18 years.

Other medicines and [nationally completed] name

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

In particular, [nationally completed name] 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 [Nationally completed name].

[Nationally completed name] 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 adjust the dose of your medicine.

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. **Pregnancy**
The use of [nationally completed name] in pregnant women is **not recommended**.

Breast-feeding
Women taking [Nationally completed name] 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, [nationally completed name] may change your reactivity, making driving or operating machinery inappropriate.

10 mg film-coated tablets:
[Nationally completed name] contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
20 mg film-coated tablets:
[Nationally completed name] contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take [nationally completed name]

Always take [nationally completed name] exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

[Nationally completed name] 10 mg film-coated tablets
Dosage

The **recommended dose** 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:

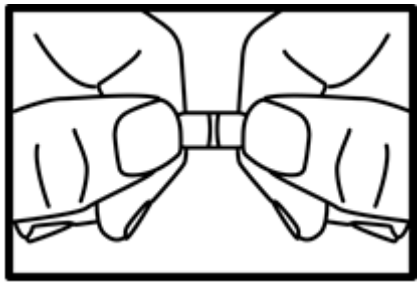
Period of intake	**Dosage once daily**
week 1	half a 10 mg tablet
week 2	one 10 mg tablet
week 3	one and a half 10 mg tablets
week 4 and beyond	two 10 mg tablets

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

[Nationally completed name] 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.
The tablet can be divided into 2 equal doses, as seen in the picture. If required, take the tablet in your hands and press the thumbs downwards, over the index fingers.



[Nationally completed name] 20 mg film-coated tablets
Dosage

The **recommended dose** 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:

Period of intake	**Dosage once daily**
week 1	quarter of a 20 mg tablet
week 2	half a 20 mg tablet
week 3	three quarters of a 20 mg tablet
week 4 and beyond	one 20 mg tablet

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

[Nationally completed name] 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.
The tablet can be divided into 4 equal doses, as seen in the picture. If required, place the tablet on a flat surface with the score lines facing upward; using your thumb, apply pressure to the tablet.

Duration of treatment

Continue to take [nationally completed name] as long as it is of benefit to you. Your doctor should assess your treatment on a regular basis.

If you take more [nationally completed name] than you should

- In general, taking too much [nationally completed name] 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 [nationally completed name], contact your doctor or get medical advice, as you may need medical attention.

If you forget to take [nationally completed name]

- If you find you have forgotten to take your dose of [Nationally completed name], 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, balance disorders, shortness of breath, 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 this medicine.

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 [nationally completed name]

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

[Nationally completed name 10 and 20 mg film-coated tablets]
Do not use this medicine after the expiry date which is stated on the blister <or bottle label> and carton after "EXP". The expiry date refers to the last day of that month.
<Once opened, the contents of the bottle should be used within 6 months.>

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 [nationally completed name] contains

{[Nationally completed name] 10 mg film-coated tablets}
- The active substance is memantine. Each film-coated tablet contains 10 mg of memantine hydrochloride which is equivalent to 8.31 mg of memantine.

- The other ingredients are lactose monohydrate, cellulose microcrystalline, silica colloidal anhydrous, magnesium stearate in the core; hypromellose (E 464), lactose monohydrate, macrogol, triacetin and titanium dioxide (E 171) in the coating.

{[Nationally completed name] 20 mg film-coated tablets}
- The active substance is memantine. Each film-coated tablet contains 20 mg memantine hydrochloride which is equivalent to 16.62 mg of memantine.
- The other ingredients are lactose monohydrate, sodium starch glycolate (type A), cellulose microcrystalline, silica colloidal anhydrous, magnesium stearate in the core; polyvinyl alcohol, macrogol, titanium dioxide (E 171), talc, iron oxide red (E 172) and iron oxide yellow (E 172) in the coating.

What [Nationally completed name] looks like and contents of the pack

{[Nationally completed name] 10 mg film-coated tablets]}
White, of oval shape (6.1 x 11.6 mm) with a breaking line on both sides.
The film-coated tablet can be divided into equal doses.

{[Nationally completed name] 20 mg film-coated tablets]}
Brown-red, of round shape (diameter 11.1 mm) with two crossed breaking lines on one side.
The film-coated tablet can be divided into equal doses.

[NL/H/2680/001-002]
The film-coated tablets are packed in transparent PVC-Aclar/Aluminium and/or transparent PVC-PVDC/Aluminium blisters or are packed in HPDE bottles with PP screw cap with tamper-evident ring and desiccant and inserted in a carton.

Pack sizes:
Blister: 7, 10, 14, 18, 20, 22, 28, 30, 40, 42, 45, 48, 49, 49x1, 50, 56, 56x1, 60, 70, 84, 90, 96, 98, 98x1, 100, 100x1, 112, 980(10x98) or 1000(20x50) film-coated tablets.
Bottle: 28, 30, 56, 98, 100 or 112 film-coated tablets.

[NL/H/2681/001-002]
The film-coated tablets are packed in transparent PVC-Aclar/Aluminium and/or transparent PVC-PVDC/Aluminium blisters or are packed in HPDE bottles with PP screw cap with tamper-evident ring and desiccant and inserted in a carton.

Pack sizes:
Blister: 7, 10, 14, 18, 20, 22, 28, 30, 40, 42, 45, 48, 49,50, 56, 60, 70, 84, 90, 96, 98, 100, 112, 980(10x98) or 1000(20x50) film-coated tablets.
Bottle: 28, 30, 56, 98, 100 or 112 film-coated tablets.

[NL/H/2682/001-002]
The film-coated tablets are packed in transparent PVC-Aclar/Aluminium and/or transparent PVC-PVDC/Aluminium blisters or are packed in HPDE bottles with PP screw cap with tamper-evident ring and desiccant and inserted in a carton.

Pack sizes:
Blister: 7, 10, 14, 18, 20, 28, 30, 42, 48, 49, 50, 56, 60, 70, 84, 96, 98, 100 or 112 film-coated tablets.
Bottle: 28, 30, 56, 98, 100 or 112 film-coated tablets.

[NL/H/2704/001]
The film-coated tablets are packed in transparent PVC-Aclar/Aluminium and/or transparent PVC-PVDC/Aluminium blisters and inserted in a carton.
Pack sizes:
Blister: 28 or 56 film-coated tablets.

[NL/H/2704/002]

The film-coated tablets are packed in transparent PVC-Aclar/Aluminium and/or transparent PVC-PVDC/Aluminium blister packs and inserted in a carton.

Pack sizes:
Blister: 28 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorization holder:
Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Nederland

Manufacturer:
Lek Pharmaceuticals d.d.
Verovškova 57
1526 Ljubljana
Slovenië

LEK S.A.
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02-672 Warschau
Polen

Salutas Pharma GmbH
Otto-von-Guericke Allee 1
39179 Barleben
Duitsland

S.C. Sandoz, S.R.L.
Str. Livezeni nr. 7A
RO-540472 Targu-Mures
Roemenië

In het Register ingeschreven onder:
Xapimant 10 mg, filmomhulde tabletten: RVG 112085
Xapimant 20 mg, filmomhulde tabletten: RVG 112086

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

Nederland:
Xapimant 10 mg, filmomhulde tabletten
Xapimant 20 mg, filmomhulde tabletten

Bulgarije: (001+003 only)
Xapimant
Xapimant

Estland:
Xapimant
Xapimant
Xapimant

Letland
Xapimant 10 mg plėvele dengtos tabletės
Xapimant 20 mg plėvele dengtos tabletės
Xapimant 10 mg/ml geriamasis tirpalas

Polen
Xapimant
Xapimant
Xapimant

Roemenië
Xapimant 10 mg comprimate filmate
Xapimant 20 mg comprimate filmate
Xapimant 10 mg/ml solu□ie orală Slovenie

Slovenië
Xapimant 10 mg filmsko obložene
tablete
Xapimant 20 mg filmsko obložene
tablete
Xapimant 10 mg/ml peroralna
raztopina

Slowakije
Xapimant 10 mg
Xapimant 20 mg
Xapimant 10 mg/ml perorálny roztok

Deze bijsluiter is voor het laatst goedgekeurd in februari 2024