

Package leaflet: Information for the patient

Valios 10 mg Orodispersible Tablets
Valios 20 mg Orodispersible Tablets
Valios 5 mg/10 mg/15 mg/20 mg Orodispersible Tablets
(Initiation pack)
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

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1. What Valios is and what it is used for

Valios 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. Valios belongs to a group of medicines called NMDA-receptor antagonists. Valios acts on these NMDA-receptors improving the transmission of nerve signals and the memory.

Valios is used for the treatment of patients with moderate to severe Alzheimer’s disease.

2. What you need to know before you take Valios

Do not take Valios:

- 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 Valios

- 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 Valios 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

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

Other medicines and Valios

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

In particular, Valios 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 Valios.

Valios 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 tubular 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 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 Valios 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, Valios may change your reactivity, making driving or operating machinery inappropriate.

Valios contains aspartame and lactose

Aspartame contains a source of phenylalanine which may be harmful for people with phenylketonuria.

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Valios

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

The recommended dose of Valios for adults and older people 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	One 5 mg tablet per day for 7 days (light pink, round, flat, speckled tablets with bevelled edges, a diameter of 7 mm and engraved with “5” on one side)
Week 2	One 10 mg tablet per day for 7 days (light pink, round, flat, speckled tablets with bevelled edges, a diameter of 9 mm and engraved with “10” on one side)
Week 3	One 15 mg tablet per day for 7 days (light pink, round, flat, speckled tablets with bevelled edges, a diameter of 11 mm and engraved with “15” on one side)
Week 4 & beyond	One 20 mg tablet per day (light pink, round, flat, speckled tablets with bevelled edges, a diameter of 12 mm and engraved with “20” on one side)

Maintenance dose

The recommended daily dose is 20 mg once a day. For continuation of the treatment please consult your doctor.

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

Valios 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 can be taken with or without food.

Valios orodispersible tablets break easily, so you should handle the tablets carefully. Do not handle the tablets with wet hands as the tablets may break up.

- Hold the blister strip at the edges and separate one blister cell from the rest of the strip by gently tearing along the perforations around it.
- Carefully peel off the backing.
- Place the tablet on your tongue. The tablet will rapidly disintegrate and can be swallowed without water.

Duration of treatment

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

If you take more Valios than you should

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

If you forget to take Valios

- If you find you have forgotten to take your dose of Valios, 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, pharmacist or nurse.

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)

- Drug hypersensitivity, headache, sleepiness, constipation, elevated liver function tests, dizziness, balance disorders, shortness of breath and high blood pressure

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Valios

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 after “EXP”. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Valios contains

The active substance is memantine hydrochloride. Each 5 mg orodispersible tablet contains 5 mg memantine hydrochloride equivalent to 4.15 mg memantine. Each 10 mg orodispersible tablet contains 10 mg memantine hydrochloride equivalent to 8.31 mg memantine. Each 15 mg orodispersible tablet contains 15 mg memantine hydrochloride equivalent to 12.46 mg memantine. Each 20 mg orodispersible tablet contains 20 mg memantine hydrochloride equivalent to 16.62 mg memantine.

The other ingredients are polacrilin, sodium hydroxide (for pH-adjustment), lactose monohydrate, cellulose, microcrystalline, mannitol (E421), croscarmellose sodium, aspartame (E951), silica, colloidal anhydrous, iron oxide red (E172), flavour peppermint [containing Maltodextrin (maize), Modified starch E1450 (waxy maize), Peppermint oil (mentha arvensis)], magnesium stearate.

What Valios looks like and contents of the pack

Valios 5 mg orodispersible tablets are presented as light pink round, flat, speckled tablets with bevelled edges, with a diameter of 7 mm and engraved with “5” on one side. Valios 10 mg orodispersible tablets are presented as light pink, round, flat, speckled tablets with bevelled edges, with a diameter of 9 mm and engraved with “10” on one side. Valios 15 mg orodispersible tablets are presented as light pink, round, flat, speckled tablets with bevelled edges, with a diameter of 11 mm and engraved with “15” on one side. Valios 20 mg orodispersible tablets are presented as light pink, round, flat, speckled tablets with bevelled edges, with a diameter of 12 mm and engraved with “20” on one side.

Valios orodispersible tablets are available in blister packs of **10 mg:** 28 orodispersible tablets
20 mg: 28 orodispersible tablets

Initiation pack of 28 orodispersible tablets containing: 7 orodispersible tablets of 5 mg, 7 orodispersible tablets of 10 mg, 7 orodispersible tablets of 15 mg, 7 orodispersible tablets of 20 mg

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Dr. Reddy’s Laboratories (UK) Ltd., 6 Riverview Road, Beverley, East Yorkshire, HU17 0LD, United Kingdom

Manufacturer

Genepharm S.A.
18th km Marathonos Ave, Pallini Attiki, 15351, Greece

This leaflet was last revised in 07/2018

DRXXXXXX
Component Code