Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

V-mantine 10 mg
V-mantine 20 mg

Orodispersible tablets

Name and quantity of active ingredient:
Each orodispersible tablet of V-mantine 10 mg contains: 10 mg memantine hydrochloride
Each orodispersible tablet of V-mantine 20 mg contains: 20 mg memantine hydrochloride

Inactive ingredients and allergens: See the section 'Important information about some of this medicine's ingredients' and section 6 'Additional information.'

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

V-mantine is intended for treating moderate to severe Alzheimer.

Therapeutic group: NMDA receptor antagonists.

V-mantine belongs to a group of medicines known as anti-dementia medicines. Memory loss in Alzheimer's disease is due to a disturbance in transmission of nerve signals in the brain. The brain contains so-called N-methyl-D-aspartate (NMDA)-receptors. These receptors are involved in transmitting nerve signals that are important in learning and memory. V-mantine acts on these NMDA-receptors improving the transmission of nerve signals and the memory.

2. Before using this medicine

Do not use this medicine if:
- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see the list of inactive ingredients in section 6).

Special warnings about using this medicine

Before taking V-mantine, tell your doctor if:

- you have a history of epilepsy (epileptic seizures).
- you have or have had impaired function of the heart and/or blood vessels (heart attack, heart failure, high blood pressure).

In these situations, your doctor will carefully monitor your treatment and will assess how well it is working on a regular basis.

- If you suffer or have suffered from impaired kidney function. Your doctor should closely monitor your kidney function and, if necessary, adapt your dose.
- If you have recently changed or intend to change your diet substantially (for example: from normal diet to vegetarian diet), or if you take large amounts of antacids.
- If you go into hospital, it is important to let your doctor at the hospital know that you are taking V-mantine.

While you are taking V-mantine, avoid taking the following medicines:

- amantadine (for the treatment of Parkinson's disease)
- ketamine (a substance used as a general anesthetic)
- dextromethorphan (a medicine used to treat cough)
- other NMDA-antagonists

Children and adolescents
This medicine is not intended for use in children and adolescents under the age of 18 years.

Other medicines and V-mantine
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- amantadine, ketamine, dextromethorphan (see the section 'Special warnings about using this medicine')
- dantrolene, baclofen (for spasms)
- cimetidine, ranitidine, procainamide, quinidine, quinine, nicotine
- hydrochlorothiazide
- anticholinergics (substances generally used to treat involuntary movements and intestinal cramps)
- medicines for epilepsy
- barbiturates (medicines used as sedatives and to induce sleep)
- dopaminergic agonists such as L-DOPA, bromocriptine (used to treat Parkinson's disease)
- neuroleptics (used in the treatment of mental disorders)
- anticoagulants

Using this medicine and food
This medicine can be taken with or without food.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, consult your doctor or pharmacist for advice before taking this medicine.
Pregnancy
The use of V-mantine in pregnant women is not recommended.
Breastfeeding
Do not breastfeed if you are taking V-mantine.

Driving and using machines
Your doctor will tell you whether your medical condition allows you to drive and to use machines safely.
Also, do not drive or operate dangerous machines while you are taking this medicine because it may affect your ability to be alert and your reaction times.

Important information about some of this medicine's ingredients
This medicine contains aspartame and lactose.
Aspartame: Each V-mantine 10 mg tablet contains 2.5 mg of aspartame. Each V-mantine 20 mg tablet contains 5 mg of aspartame.
Aspartame is a source of phenylalanine. It may harm you if you have phenylketonuria (PKU) which is a rare genetic disorder in which phenylalanine builds up because the body is unable to clear it out normally.
Lactose: If your doctor has told that you have an intolerance to certain sugars, consult your doctor before taking this medicine.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions.Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Only your doctor will determine your dose and how you should take this medicine. The recommended dosage is usually:

Recommended dose in adults and the elderly- 20 mg a day.
In order to reduce the risk of side effects this dose is achieved gradually by the following scheme:

week 1	5 mg a day
week 2	10 mg a day
week 3	15 mg a day
week 4 and onward	20 mg a day

The starting dose is half a tablet of V-mantine 10 mg a day for the first week.
In the second week, one tablet of V-mantine 10 mg a day.
In the third week, one and a half tablets of V-mantine 10 mg a day.
From the fourth week on, 1 tablet of V-mantine 20 mg or 2 tablets of V-mantine 10 mg a day.

Dosage in patients with impaired kidney function:
Patients with slightly impaired kidney function (creatinine 50-80 ml/min) do not need to have their dose adjusted.
The dose for patients with moderately impaired kidney function (creatinine 30-49 ml/min) is 10 mg a day. If the medicine is well-tolerated after 7 days of treatment, the dose can be increased to 20 mg a day.
The dose for patients with severely impaired kidney function (creatinine 5-29 ml/min) is 10 mg a day.

Do not exceed the recommended dose.
How to use this medicine:
Take this medicine once a day. Take the medicine at the same time every day. This medicine can be taken with or without food.
Directions for use:
V-mantine Orodispersible tablets break easily so handle them with care. Do not handle the tablets with wet hands, because they might break.

- Hold the edge of the blister pack and separate one blister from the other tablets in the blister pack by gently tearing along the marking.
- Gently peel the backing off.
- Place the tablet on your tongue. The tablet will dissolve easily and you will be able to swallow it without water.

If you have accidentally taken a higher dose, see your doctor or get medical attention. Taking an overdose is usually not harmful, but you may experience side effects (see the section ‘Side effects’).
If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, wait and take your next dose at the usual time.
Never take a double dose!
Take this medicine at regular times as your doctor has told you.

Complete the course of treatment your doctor has prescribed.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using V-mantine may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Common side effects (affect 1-10 users in 100):
dizziness, balance disorders, headache, constipation, sleepiness, high blood pressure, elevated liver function tests, shortness of breath, allergic reaction to the medicine.

Uncommon side effects (affect 1-10 users in 1,000):
hallucinations, confusion, tiredness, abnormal gait, vomiting, fungal infections, venous blood clotting, heart failure.

Very rare side effects (affect less than one in 10,000 users):
seizures.

Side effects of unknown frequency (the frequency of these effects has not been established yet):
psychotic reactions, inflammation of the pancreas, inflammation of the liver (hepatitis).

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

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions
Do not store above 30°C.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines that have expired or that you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Mannitol, microcrystalline cellulose, polacrilin, lactose monohydrate, croscarmellose sodium, magnesium stearate, aspartame, silica colloidal anhydrous, flavor peppermint, iron oxide red (E172), sodium hydroxide, purified water.

What the medicine looks like and contents of the pack:
V-mantine 10 mg: flat, round, speckled, light pink tablet with '10' engraved on one side.
V-mantine 20 mg: flat, round, speckled, light pink tablet with '20' engraved on one side.

Tablets are available in blister packs of: 10, 14, 28, 42, 50, 56, 70, 84, 98, 100, 112 tablets.
Not all pack sizes may be marketed.

Registration holder's name and address: Vitamed Pharmaceutical Industries Ltd., 6 Hatahana St., POB 114, Binyamina, 3055002.
Manufacturer's name and address: Genepharm S.A, 18km , Marathon Avenue, Pallini, Attikis, Greece

The format of this leaflet was determined by the Ministry of Health and its content has been reviewed and approved by the Ministry of Health in April 2019.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
V-mantine 10 mg: 34808
V-mantine 20 mg: 34810