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

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 in the medicine- see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

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 treatment of moderate to severe Alzheimer's disease.

Therapeutic group: NMDA receptor antagonist.

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 NMDA-receptors, thus 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 this medicine contains (see section 6 "Additional information").
- You are breastfeeding.

Special warnings about using this medicine

Before using V-Mantine, tell the doctor if:

- You have a history of epilepsy (epileptic seizures).
- You have recently experienced a myocardial infarction (heart attack), or if you are suffering from heart failure or uncontrolled hypertension (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.

- You suffer from impaired kidney function (kidney problems). Your doctor should closely monitor your kidney function and, if necessary, adapt your dosage.

- You suffer from states of renal tubulary acidosis (RTA, an excess of acid-forming substances in the blood due to poor kidney function) or severe urinary tract infections. Your doctor may need to adjust the medicine dosage to your condition.

Avoid concomitant use of V-Mantine and the following medicines:
- Amantadine (for 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:
V-Mantine is not recommended for children and adolescents under the age of 18 years.

Drug interactions:
If you are taking or have recently taken other medicines, including non-prescription medications and nutritional supplements, tell the doctor or pharmacist. Particularly, inform your doctor or pharmacist if you are taking the following medicines, since **V-Mantine** may change their effects and their dosage may need to be adjusted by your doctor:

- Amantadine, Ketamine, Dextromethorphan (see section "Special warnings about the use of this medicine")
- Dantrolene, Baclofen
- Cimetidine, Ranitidine, Procainamide, Quinidine, Quinine, Nicotine
- Hydrochlorothiazide (or any combination with Hydrochlorothiazide)
- Anticholinergics (generally used to treat movement disorders and intestinal cramps)
- Medicines for epilepsy (for prevention and relief of seizures)
- Barbiturates (generally used to induce sleep)
- Dopaminergic agonists such as L-DOPA, Bromocriptine
- Neuroleptics (for treatment of mental disorders)
- Oral anticoagulants

If you go to a hospital, inform your doctor that you are taking **V-Mantine**.

Using this medicine and food
This medicine can be taken with or without food.
You should inform your doctor if you have recently changed or intend to change your diet substantially (e.g. from normal diet to vegetarian diet), as your doctor may need to adjust the dosage of your medicine.

Pregnancy and breastfeeding:
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, ask your doctor or pharmacist for advice before using 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 or to use machines safely.
Also, **V-Mantine** may change your ability to react, therefore driving or operating machines is not recommended.

Important information about some of the ingredients of this medicine
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 the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.
The dosage and manner of treatment will be determined by the doctor only. The recommended dosage is usually:
The recommended dosage for adult and elderly patients -20 mg per day.
In order to reduce the risk of side effects, this dosage should be reached gradually by the following scheme:

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

The starting dose is one tablet of Memantine Hydrochloride 5 mg per day for the first week.
In the second week, one tablet of Memantine Hydrochloride 10 mg per day.
In the third week, one tablet of Memantine Hydrochloride 15 mg per day.
From the fourth week on, one tablet of Memantine Hydrochloride 20 mg or 2 tablets of Memantine Hydrochloride 10 mg per day.

Dosage in patients with impaired kidney function:
Patients with mild renal dysfunction (creatinine clearance 50-80 ml/min) do not need dosage adjustment.
The daily dosage for patients with moderate renal dysfunction (creatinine clearance 30-49 ml/min) is 10 mg. If the medicine is well tolerated after 7 days of treatment, the dosage can be increased to 20 mg a day.
The dosage for patients with severe renal dysfunction (creatinine clearance 5-29 ml/min) is 10 mg per day.

Do not exceed the recommended dose.

How to use this medicine:
Take the medicine once a day, at the same time every day, 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 dissolve.

- Hold the edge of the blister pack and separate one blister cell 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 section 4 "Side effects").
If a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forget to take the medicine at the scheduled time, do not take a double dose. Take your next dose at the usual time and consult your doctor.
Take this medicine at regular times as your doctor has told you.
Adhere to the treatment as recommended by your doctor.
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 a medicine. Wear glasses if you need them.

If you have any further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use of **V-Mantine** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them. In general, the observed side effects are mild to moderate.

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

Uncommon side effects (effects that appear in 1-10 out of 1,000 users):
Tiredness, fungal infections, confusion, hallucinations, vomiting, abnormal gait, heart failure and venous blood clotting (thrombosis/ thromboembolism).

Very rare side effects (effects that appear in less than 1 out of 10,000 users):
Seizures.

Side effects of unknown frequency (effects for which a frequency has not yet been determined):
Inflammation of the pancreas, inflammation of the liver (hepatitis) and psychotic reactions.

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

If a side effect appears, if one of the side effects worsen or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Report of side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report adverse effects and problems associated with medications and drugs" on the Ministry of Health home page (www.health.gov.il), which links to an online form for reporting side effects, or by following the link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/ or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the 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 medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines 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 (E 172), Sodium Hydroxide, Purified Water.

What the medicine looks like and what the package contains:
V-Mantine 10 mg: round, flat, speckled, light pink tablet with beveled edges, with "10" engraved on one side.
V-Mantine 20 mg: round, flat, speckled, light pink tablet with beveled edges, 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 Hatachana St., POB 114, Binyamina, 3055002, Israel.

Manufacturer's name and address:
Genepharm S.A., 18TH KM, Marathonos Avenue, 15351 Pallini, Greece.

Revised in September 2022 according to MOH guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health:
V-Mantine 10 mg: 162-05-34810-00
V-Mantine 20 mg: 162-06-34808-00