PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Nemdatine 10 mg

Film-coated tablets

Composition:
Each film-coated tablet contains:
Memantine Hydrochloride 10 mg

Nemdatine 20 mg

Film-coated tablets

Composition:
Each film-coated tablet contains:
Memantine Hydrochloride 20 mg

For information regarding inactive ingredients, see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine.

If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

1. What is the medicine intended for?

Nemdatine is intended for the treatment of moderate to severe Alzheimer's disease.

Therapeutic class: NMDA receptor antagonist.

Nemdatine belongs to a group of medicines for the treatment of dementia. The memory loss typical of Alzheimer's disease is due to a disturbance in transmission of nerve signals in the brain. The brain contains receptors called NMDA receptors. These receptors are involved in transmission of nerve signals that are important for learning and memory. Nemdatine acts on NMDA receptors, thus improving the transmission of nerve signals and the memory.

2. Before using the 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 (for the list of inactive ingredients see section 6 – "Additional information").

Special warnings regarding the use of the medicine

Before treatment with Nemdatine, inform the doctor if:

- You have a history of epilepsy (epileptic seizures).
- You have recently had a myocardial infarction (heart attack), or if you are suffering from heart failure or from uncontrolled hypertension. In the conditions mentioned above, the doctor will carefully monitor the treatment with the medicine and will assess its efficacy on a regular basis.
- You suffer from renal impairment (kidney problems). The doctor will have to closely monitor your kidney function and adjust the dosage if necessary.
- If you are suffering from states of renal tubular acidosis (RTA, an excess of acid-forming substances in the blood due to poor kidney function) or severe urinary tract infections, the doctor may need to adjust the dosage of the medicine to your condition.

Concomitant use of Nemdatine and the following medicines should be avoided:

- Amantadine (for the treatment of Parkinson's disease).
- Ketamine (a substance used for general anesthesia).
- Dextromethorphan (a medicine for the treatment of cough).
- Other NMDA antagonist medicines.

Children and adolescents

Nemdatine 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 medicines and nutritional supplements, tell the doctor or the pharmacist. It is especially important to inform the doctor or pharmacist if you are taking the following medicines, since Nemdatine may change their effects and the doctor may need to adjust their dosage:

- Amantadine, ketamine, dextromethorphan (see the section "Special warnings regarding the use of the medicine").
- Dantrolene, baclofen.
- Cimetidine, ranitidine, procainamide, quinidine, quinine, nicotine.
- Hydrochlorothiazide (or any combination with hydrochlorothiazide).
- Anticholinergic medicines (commonly used to treat movement disorders and intestinal cramps).
- Medicines for the treatment of epilepsy (to prevent and relieve seizures).
- Barbiturates (commonly used to induce sleep).
- Dopamine agonist such as L-DOPA, bromocriptine.
- Neuroleptic medicines (for the treatment of mental disorders).
- Oral anticoagulants.

If you go to a hospital for treatment, inform your doctor that you are taking Nemdatine.

Use of the medicine and food

The medicine may be taken with or without food.

Inform your doctor if you have recently changed or if you intend to change your diet substantially (such as: transition from a regular diet to a vegetarian diet), as your doctor may need to adjust the dosage of the medicine accordingly.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult the doctor or pharmacist before taking this medicine.

Pregnancy

The use of memantine in pregnant women is not recommended.

Breastfeeding

Do not breastfeed if you are taking Nemdatine.

Driving and operating machinery

The doctor will tell you whether your medical condition allows you to drive or to operate machinery safely.

Furthermore, Nemdatine may alter your ability to react, therefore driving or operating machinery is not recommended.

Important information about some of the ingredients of the medicine

The medicine Nemdatine contains lactose. If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The dosage and treatment regimen will be determined only by the doctor. The generally accepted dosage is:

The recommended dosage for adults and the elderly – 20 mg per day.

In order to reduce the risk of side effects, the dosage should be taken gradually according to the following plan:

Week 1	5 mg per day.
Week 2	10 mg per day.
Week 3	15 mg per day.
Week 4 onwards	20 mg per day.

The initial dose is half a tablet of Nemdatine 10 mg per day during the first week.

In the second week, one Nemdatine 10 mg tablet per day.

In the third week, one and a half Nemdatine 10 mg tablets per day.

From the fourth week onwards, one Nemdatine 20 mg tablet or two Nemdatine 10 mg tablets per day.

Dosage for patients with impaired kidney function:

In patients with mild impaired kidney function (creatinine clearance is 50-80 ml per minute), dosage adjustment is not required.

In patients with moderate impaired kidney function (creatinine clearance is 30-49 ml per minute), the daily dosage is 10 mg. If there is tolerance to the medicine after 7 days of treatment, dosage may be increased to 20 mg daily.

In patients with severe impaired kidney function (creatinine clearance 5-29 ml per minute), the daily dosage is 10 mg.

Do not exceed the recommended dose.

Method of use: The tablet should be swallowed with some water. The medicine may be taken with or without food.

The medicine should be taken once a day. The medicine should be taken at the same time each day.

Nemdatine 10 mg tablet may be halved (the tablet has a score line). There is no information regarding pulverization or chewing.

If you accidentally took a higher dosage, refer to a doctor or seek medical attention. Taking an overdose will usually not result in any harm, but you may experience side effects (see section 4 – "Side effects"). If a child swallowed this medicine by mistake, immediately go to the doctor or the emergency room of the hospital and bring the package of the medicine with you.

If you forget to take this medicine at the required time, do not take a double dose, take the next dose at the regular time and consult the doctor.

This medicine should be taken at set intervals as determined by the treating doctor.

Follow the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting a doctor.

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

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Nemdatine may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them. In general, the side effects observed are mild to moderate.

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

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

Very rare side effects (side effects that occur in less than one out of 10,000 users):
Convulsions.

Side effects with unknown frequency (side effects whose 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 thoughts and suicide. Such events have also been reported in patients taking Nemdatine.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il.

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Storage conditions: do not store above 25°C.

Do not dispose of medicines in household trash or the toilet. In order to protect the environment, ask the pharmacist how to dispose of medicines that are no longer required or that have expired.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Nemdatine 10 mg:
Microcrystalline Cellulose, Talc, Crospovidone Type A, Hypromellose 6cP, Titanium Dioxide, Lactose Monohydrate, Magnesium Stearate, Macrogol 3350, Triacetin.

Nemdatine 20 mg:
Microcrystalline Cellulose, Talc, Crospovidone Type A, Hypromellose 6cP, Titanium Dioxide, Lactose Monohydrate, Magnesium Stearate, Macrogol 3350, Triacetin, Iron Oxide Red, Iron Oxide Yellow.

What does the medicine look like and what are the contents of the package:

Nemdatine 10 mg: a white, biconvex, film-coated, capsule-shaped tablet with a score line. The markings "M" and "10" are debossed on one side, and are separated by the score line.

Nemdatine 20 mg: a dark pink, biconvex, film-coated, oval tablet. The marking "M 20" is debossed on one side.

Package sizes:

Nemdatine 10 mg: 28 or 56 tablets in a tray (blister) package.

Nemdatine 20 mg: 28 or 56 tablets in a tray (blister) package.

Not all package sizes may be marketed.

Marketing authorization holder and address:
Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020.

Name and address of the manufacturer:
Actavis Ltd., Zejtun, Malta.

The leaflet was revised in October 2021 in accordance with the Ministry of Health guidelines.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Nemdatine 10 mg: 157-02-34401

Nemdatine 20 mg: 157-03-34417

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