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

The medicine is dispensed with a doctor's prescription only

Nemdatine 20 mg	**Nemdatine 10 mg**
Coated tablets	**Coated tablets**
Active ingredient and its quantity:	**Active ingredient and its quantity:**
Each tablet contains: Memantine Hydrochloride 20mg	Each tablet contains: Memantine Hydrochloride 10mg

For a list of inactive ingredients, see 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.
- The medicine is intended for adults (over 18 years old).

1. What is the medicine intended for?

Nemdatine is intended for treatment of moderate to severe Alzheimer's disease. Nemdatine belongs to a group of anti-dementia medicines. Memory loss, which is typical for Alzheimer's disease, is caused by a disturbance in transmission of nerve signals in the brain. The brain contains so-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.

Therapeutic class:
NMDA-receptor antagonist.

2. Before using the medicine

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

❗ 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 suffer or suffered in the past from an impairment in cardiac and/or blood vessels function (heart attack, heart failure, high blood pressure).

In these situations, the doctor will carefully supervise the medicinal therapy and observe its efficiency on a regular basis.

- You suffer or suffered in the past from renal impairment (kidney problems). The doctor will have to monitor your kidney function closely and adjust the dosage if necessary.
- You have recently done or you are planning to do radical changes in your daily diet (e.g. going from regular diet to vegetarian diet) or if you are taking large amounts of antacids.
- You are admitted to a hospital. It is important to inform the doctor in the hospital that you are taking Nemdatine.

While taking Nemdatine, you should avoid taking the following medicines:

- Amantadine (for treatment of Parkinson's disease).
- Ketamine (a substance used as a general anesthetic).
- Dextromethorphan (a cough medicine).
- Other NMDA antagonists.

❗ If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the doctor or the pharmacist. Especially inform the doctor or pharmacist if you are taking:

- Amantadine, ketamine, dextromethorphan (see section "Special warnings regarding the use of the medicine").
- Dantrolene, baclofen (for spasms).
- Cimetidine, ranitidine, procainamide, quinidine, quinine, nicotine.
- Hydrochlorothiazide.
- Anticholinergics (substances generally used to treat movement disorders and intestinal cramps).
- Medicines for treatment of epilepsy.
- Barbiturates (sedatives or sleep medicines).
- Dopaminergic agonists like L-DOPA, bromocriptine (for treatment of Parkinson's disease).
- Neuroleptics (for treatment of mental disorders).
- Anticoagulants.

❗ Use of the medicine and food
The medicine may be taken with or without food.

❗ Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, ask the doctor or pharmacist for advice 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. In addition, do not drive or operate dangerous machinery while using the medicine, since it might affect your alertness and time of response.

❗ Important information about some of the ingredients of the medicine
Each tablet of Nemdatine 10 mg contains about 0.95 mg of lactose monohydrate.
Each tablet of Nemdatine 20 mg contains about 1.89 mg of lactose monohydrate.
If the doctor tells you that your are sensitive to certain sugars, refer to the doctor before taking Nemdatine.

3. How should you use the medicine?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.
The dosage and treatment regimen will be determined only by the doctor.
Dosage:
The generally accepted dosage is:
The recommended dosage for adults and older people - 20 mg a day.
In order to reduce the risk for side effects, take your dosage gradually according to the following schedule:

Week 1	5 mg a day.
Week 2	10 mg a day.
Week 3	15 mg a day.
Week 4 and beyond	20 mg a day.

The initial dose is half a Nemdatine 10 mg tablet a day during the first week.
On the second week, one Nemdatine 10 mg tablet a day.
On the third week, one and a half Nemdatine 10 mg tablet a day.
From the fourth week and beyond, one Nemdatine 20 mg tablet or two Nemdatine 10 mg tablets a day.
Dosage for patients with impaired kidney function:
In patients with mild renal impairment (creatinine clearance is 50-80 ml/min), dosage adjustment is not required. In patients with moderate renal impairment (creatinine clearance is 30-49 ml/min), the daily dosage is 10 mg a day. If tolerance to the medicine develops after 7 days of treatment, the dosage may be increased to 20 mg a day. In patients with severe renal impairment (creatinine clearance is 5-29 ml/min), the daily dosage is 10 mg a day.
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 tablets may be halved (the tablet has a score line). There is no information regarding pulverization or chewing.
If you accidentally take a higher dosage, you should refer to a doctor or seek medical help. Taking too much Nemdatine should usually not cause any harm to you, but you may experience side effects. (see the Side Effects section).
If you have forgotten to take the medicine as scheduled, wait and take your next dose at the usual time. Never take two doses together!
This medicine should be used at set intervals as determined by the attending doctor.
You should complete the treatment recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the 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.
Common side effects (frequency of up to 1:100 patients):
Dizziness, balance disorders, headache, constipation, sleepiness, high blood pressure, rise in the results of liver function tests, shortness of breath, allergic reaction to the medicine.
Uncommon side effects (frequency of up to 1:1,000 patients):
Hallucinations, confusion, tiredness, abnormal gait, vomiting, fungal infections, venous blood clotting (thrombosis/ thromboembolism), heart failure.
Rare side effects (frequency below 1:1,000 patients):
Seizures.
Side effects with unknown frequency:
Psychotic reactions, inflammation of the pancreas, inflammation of the liver (hepatitis).
Alzheimer's disease has been associated with depression, suicidal ideation and suicide. These events have also been reported in patients treated with 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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.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:**Do not store at a temperature above 25˚C.
- Do not throw away any medicines via wastewater or household waste. In order to protect the environment, ask your 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, Magnesium Stearate, Hypromellose 6cP, Titanium Dioxide, Lactose Monohydrate, Macrogol 3350, Triacetin.

Nemdatine 20 mg

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

Each tablet of Nemdatine 10 mg contains about 0.95 mg of lactose monohydrate.
Each tablet of Nemdatine 20 mg contains about 1.89 mg of lactose monohydrate.
See also the "Important Information About Some of the Ingredients of the Medicine" Section.

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

Nemdatine 10 mg: A white, scored, coated, capsule-shaped tablet. The imprint "M" and "10" appears on one side.

Nemdatine 20 mg: A dark pink, coated, oval-shaped tablet. The imprint "M 20" appears on one side.

Size of package

A cardboard box containing a blister.
Each package of Nemdatine 10 mg contains: 28, 30, 42, 50, 56, 60, 98, 112 tablets.
Each Nemdatine 20 mg package contains: 28, 42, 56, 98 Tablets.
Not all package sizes may be marketed.

License holder:

Abic Marketing Ltd. P.O.B 8077 Netanya, 42504.

Manufacturer:

Actavis Ltd. Malta, BLB 016 Bulebel Industrial Estate, Zejtun ZTN 3000, Malta

This leaflet was checked and approved by the Ministry of Health on: September 2016.
Registration number 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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