Package leaflet: Information for the patient
NEIROMIDIN 20 mg Tablets
Ipidacrinum

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

1. What *Neiromidin* is and what it is used for
The active substance of *Neiromidin* – ipidacrine is a cholinesterase inhibitor, which is used for the treatment of peripheral nervous system diseases (neuritis, polyneuritis, polyneuropathy, polyradiculoneuropathy, myasthenia and myasthenic syndrome of different origin); bulbar paralysis and paresis; during the recovery period after organic CNS impairments with movement disturbances, in complex therapy of demyelinating nervous system diseases; for the treatment of memory disorders of various origin (Alzheimer's disease and other forms of senile dementia) as well as for the treatment of intestinal atonia.

2. What you need to know before you take *Neiromidin*

Do not take *Neiromidin*
- if you are allergic (hypersensitive) to ipidacrine or any of the other ingredients of this medicine (listed in section 6.);
- if you have epilepsy;
- if you have extrapyramidal diseases with hyperkinesis (muscle spasm of the tongue, face, neck and back);
- if you have stenocardia (acute pain attack in heart region and/or behind the breastbone);
- if you have significant bradycardia (before starting the treatment pulse at rest is less than 50 beats per minute);
- if you have bronchial asthma;
- if you have intestinal or urinary tract obstruction;
- if you have vestibular (perception of body state change) disorders;
- if you have exacerbation of gastric ulcer or duodenal ulcer;
- if you are breastfeeding;
- if you are pregnant.

Paediatric population
The safety of this medicine in children and adolescents under 18 years of age has not been established so far.The expected benefit of treatment should be carefully weighed against the fact that there are no adequate clinical studies regarding safety of the preparation's use in children.

Warnings and precautions
Talk to your doctor or pharmacist before taking *Neiromidin*.
Tell your doctor if you have or had gastric ulcer, duodenal ulcer, thyrotoxicosis, cardiovascular system disease, respiratory tract disease.

Other medicines and *Neiromidin*
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Neiromidin in combination with CNS depressing medicines increases the sedative effect. *Neiromidin* activity and adverse effects increase when used concomitantly with other cholinesterase inhibitors and M-cholinomimetic compounds. The risk of cholinergic crisis increases in patients with *Myasthenia gravis*, if *Neiromidin* is taken concomitantly with other cholinergic preparations. β-adrenoblockers taken before the treatment with *Neiromidin* increase the risk of bradycardia. *Neiromidin* can be used in combination with cerebrolysin.

Taking *Neiromidin* with food, drink and alcohol
Alcohol increases the adverse effects of the medicine.

Pregnancy, breast-feeding and fertility
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.
The medicine increases uterine tonus and may cause premature labor activity, therefore the administration of the medicine is contraindicated during pregnancy.
Administration is contraindicated during breast-feeding.

Driving and using machines
Since *Neiromidin* may cause sedative effect, persons, who feel that, are not recommended to drive and use machines during medicine use.

***Neiromidin* contains lactose**
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking *Neiromidin 20 mg Tablets.*

3. How to take *Neiromidin*

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Neiromidin 20 mg Tablets should be taken orally, with glass of water.
In cases of peripheral nervous system diseases, myasthenia and myasthenic syndrome: orally – 10-20 mg (half-tablet – one tablet) 1-3 times daily. The treatment course is 1-2 months. If necessary, the treatment course may be repeated several times with interval of 1-2 months.
In order to prevent the development of myasthenic crisis in case of severe affections of neuromuscular transmission, 15-30 mg (1-2 ml) of *Neiromidin 15 mg/ml Solution for injection*

should be administered for a short period. The treatment should be continued with *Neiromidin 20 mg Tablets* increasing the dose up to 20-40 mg 5-6 times daily.

In cases of memory disorders of various origin (Alzheimer's disease and other forms of senile dementia): the dose and duration of the treatment course should be determined individually, maximal daily dose may be up to 200 mg, duration of the treatment course is from one month to one year.

For treatment and prophylaxis of intestinal atonia: 20 mg 2-3 times daily during 1-2 weeks.

Consult your doctor if you think that drug effect is too strong or too weak.

If you take more *Neiromidin* than you should
If you have taken more *Neiromidin* than you should, immediately contact your doctor.
In case of serious overdose, "cholinergic crisis" may develop with the following symptoms: bronchospasms, eye lacrimation, heavy sweating, myosis, nystagmus (fast, uncontrolled eyeball movement), spontaneous defecation and urination, vomiting, bradycardia, heart block, arrhythmia, hypotension, anxiety, agitation, sense of fear, ataxia, incoherent speech, drowsiness, weakness, convulsion and coma. The symptoms may be mild.

If you forget to take *Neiromidin*
During the next administration of the drug, take the usual dose.
Do not take a double dose to make up for a forgotten dose.

If you stop taking *Neiromidin*
If you stop taking the medicine before the end of the course as doctor told you, desirable therapeutical effect may not be reached.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common (may affect up to 1 in 10 people):
palpitation, bradycardia;
hypersalivation, nausea;
increased sweating.

Uncommon (may affect up to 1 in 100 people):
using high doses – dizziness, headache, drowsiness;
increased bronchial secretion;
using high doses –vomiting;
using high doses –allergic skin reactions (itch, rash);
using high doses – muscle cramps;
using high doses – weakness.

Rare (may affect up to 1 in 1000 people):
diarrhea, epigastric pain.

Not known (cannot be estimated from the available data)
hypersensitivity

In cases of undesirable effects, the dose should be decreased or the administration should be discontinued for a short period (1-2 days). Hypersalivation and bradycardia can be decreased using M-cholinoblockers (atropine and others). Doctor can prescribe medications to reduce the 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.

5. How to store *Neiromidin*

Do not store above 25 °C. Store in the original package in order to protect from light and moisture.
Keep out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton after "Exp.:". The expiry date refers to the last day of that month.
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 *Neiromidin* contains

The active substance is ipidacrine hydrochloride (Ipidacrini hydrochloridum).
Each tablet contains 20 mg of ipidacrine hydrochloride.
The other ingredients are lactose, potato starch, calcium stearate.

What *Neiromidin* looks like and contents of the pack

White or almost white, round, flat tablets with bevelled edges.
10 tablets per blister, 5 blisters (50 tablets) in the carton pack.

Marketing Authorisation Holder

Company name: **Joint-Stock Company "Olainfarm"**
Address: **5 Rupnicu Street, Olaine, LV-2114**
Country: **Latvia**

Authorised Manufacturer

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