Package leaflet: Information for the user

NEIROMIDIN® 20 mg tablets
Ipidacrine hydrochloride

Read all of this leaflet carefully before you start using 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.
- 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. 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

Active substance of NEIROMIDIN (ipidacrine hydrochloride) is a reversible cholinesterase inhibitor, which is used for:
- peripheral nervous system diseases (neuritis, polyneuritis, polyneuropathy, polyradiculoneuritis, myasthenia and myasthenic syndrome of different origin);
- some kinds of paralysis and paresis;
- rehabilitation period after organic central nervous system (CNS) impairments with movement disturbances;
- complex therapy of demyelinizing nervous system diseases;
- memory disorders of various origin (Alzheimer's disease and other forms of senile dementia);
- intestinal atonia.

2. What you need to know before you use NEIROMIDIN

Do not use NEIROMIDIN:
- if you are allergic to ipidacrine hydrochloride or any of the other ingredients of this medicine (listed in section 6);
- if you have epilepsy;
- if you have extrapyramidal disorders with hyperkinesis (tongue, face, neck and back muscle spasms);
- if you have angina pectoris (acute pain attack in heart region and/or behind chest bone);
- if you have pronounced bradycardia (pulse in rest state is lower than 50 beats per minute before beginning of treatment);

– if you have bronchial asthma;
– if you have intestine and urinary tract obstruction;
– if you have exacerbation of gastric ulcer or duodenal ulcer;
– if you have vestibular disorders (perception of body state change);
– if you are pregnant;
– if you are breastfeeding.

Warnings and precautions
Talk to your doctor before using NEIROMIDIN if you have or have ever had:
– gastric ulcer;
– duodenal ulcer;
– thyrotoxicosis;
– diseases of cardiovascular system;
– respiratory tract diseases.

Children and adolescents
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.

Other medicines and NEIROMIDIN
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

– Use of NEIROMIDIN in combination with CNS depressing preparations increases the sedative effect.
– NEIROMIDIN activity and adverse effects are increased if the preparation is used concomitantly with other cholinesterase inhibitors and M-cholinomimetic compounds.
– The risk of the cholinergic crisis development may increase in patients with myasthenia gravis, if NEIROMIDIN is used concomitantly with other cholinergic preparations.
– If β-adrenoblockers are taken before the therapy with NEIROMIDIN, risk of bradycardia is increased.
– Cerebrolysin improves mental effect of NEIROMIDIN.

NEIROMIDIN with food, drink and alcohol
Alcohol increases the adverse effects of NEIROMIDIN.

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 for advice before using this medicine.
Pregnancy
NEIROMIDIN increases uterine tone and can lead to premature delivery. Therefore, it should not be used during pregnancy (see "*Do not use NEIROMIDIN*").
Breastfeeding
The medicine should not be used if you are breast-feeding (see "*Do not use NEIROMIDIN*").

Driving and using machines
Since NEIROMIDIN may produce sedative effect, caution is advised when driving and using potentially dangerous machines.

NEIROMIDIN 20 mg tablets contain lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to use NEIROMIDIN

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

NEIROMIDIN 20 mg tablets are taken orally. Tablet should be swallowed with water.

Peripheral nervous system diseases, myasthenia and myasthenic syndrome
NEIROMIDIN 20 mg tablets are administered orally in a dose of 10-20 mg (½ or 1 tablet) 1-3 times daily.

The treatment course continues for 1-2 months and, if necessary, the treatment course may be repeated several times after 1-2 months interval according to your doctor instructions.

To prevent development of myasthenic crisis in case of severe disorders of neuromuscular transmission, 15-30 mg (1-2 ml of NEIROMIDIN 15 mg/ml solution for injection) is administered parenterally for a short time.
Treatment is continued with NEIROMIDIN 20 mg tablets and the dose is increased up to 20-40 mg 5-6 times daily.

Memory disorders of various origin (Alzheimer's disease and other forms of senile dementia)
The dose and duration of the treatment course will be determined individually by your doctor. Maximum daily dose may reach 200 mg. Duration of treatment course is from one month to one year according to your doctor instructions.

Treatment and prevention of intestinal atonia
Dose is 20 mg (1 tablet) 2-3 times daily for 1-2 weeks.

If you feel that effect of NEIROMIDIN is too strong or too weak, talk to your doctor.

If you use more NEIROMIDIN than you should
If you have used more NEIROMIDIN than you should, seek medical attention immediately. In case of serious overdose, "cholinergic crisis" may develop with the following symptoms: bronchospasm, eye lacrimation, increased sweating, constricted eye pupils, nystagmus (fast, uncontrolled eyeball movement), unconscious defecation and urination, vomiting, decreased heart rate, heart block, arrhythmia, decreased blood pressure, restlessness, anxiety, agitation, sense of fear, movement and balance disorders, slurred speech, drowsiness, weakness, convulsions and coma. Intensity of symptoms can be mild.

If you forget to use NEIROMIDIN
Skip the missed dose and use next dose at usual time. Do not take a double dose to make up for a forgotten dose.

If you stop using NEIROMIDIN
If you stop taking medicine before the end of the prescribed therapy course by your doctor, desirable therapeutic effect will not be reached.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

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

Common (affecting less than 1 in 10 patients):
- palpitation, decreased heart rate (bradycardia).
- hypersalivation, nausea.
- increased sweating.

Uncommon (affecting less than 1 in 100 patients):
- dizziness, headache, drowsiness (when using high doses).
- hypersecretion of bronchi.
- vomiting (when using high doses).
- allergic skin reactions (itch, urticaria) (when using high doses).
- weakness (when using high doses).
- muscular cramps (when using high doses).

Rare (affecting less than 1 in 1,000 patients):
- diarrhoea, pain in epigastria.

Not known (cannot be estimated from the available data):
- hypersensitivity reactions (including allergic dermatitis, anaphylactic shock, asthma, toxic epidermal necrolysis, erythema, urticaria, wheezing, swelling of the larynx).

In cases of undesirable effects, your doctor may decrease the dose or advice to interrupt use of this medicine for a short period (1-2 days). Hypersalivation and bradycardia can be decreased using M-cholinoblockers (atropine and others). Your doctor can prescribe medications to reduce side effects.

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

5. How to store NEIROMIDIN

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on packaging. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from light and moisture.

6. Contents of the pack and other information

What NEIROMIDIN contains
The active substance is ipidacrine hydrochloride.
Each tablet contains 20 mg of ipidacrine hydrochloride.

The other ingredients are:
Lactose monohydrate, potato starch and calcium stearate.

What NEIROMIDIN looks like and contents of the pack
White or almost white, round, flat tablets with bevelled edges.
10 tablets in blister. 5 blisters (50 tablets) in cardboard box together with package leaflet.

Marketing authorisation holder and manufacturer
JSC "Olainfarm"
5 Rupnicu Street, Olaine, LV-2114, Latvia
Tel.: +371 67013705
Fax: +371 67013777
olainfarm@olainfarm.com

This leaflet was last revised in 01/2019.