

PACKAGE LEAFLET: INFORMATION FOR THE USER

RODAVAN N

50 mg tablet

DIMENHYDRINATE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What RODAVAN N is and what it is used for
2. Before you take RODAVAN N
3. How to take RODAVAN N
4. Possible side effects
5. How to store RODAVAN N
6. Further information

1. WHAT RODAVAN N IS AND WHAT IT IS USED FOR

RODAVAN N is a medicine (antihistamine) that contains the active ingredient dimenhydrinate.

It is applied for the prevention and treatment of nausea, vomiting and / or dizziness associated to motion sickness.

It is intended for adults and children over 2 years.

2. BEFORE YOU TAKE RODAVAN N

Do not take RODAVAN N

- If you are allergic to dimenhydrinate or any of the other ingredients;
- If you have known allergies to antihistamines;
- If you suffer from some form of glaucoma (high blood pressure in the eye);
- If you have difficulties with urination due to prostate disease or urinary tract.
- This medicine should not be used during the period of breast-feeding, unless your doctor decides otherwise.

Take special care with RODAVAN N

Do not use this medicine if you have bronchial asthma.

In the case of long-term liver or kidney disease, consult your doctor so he/she can adjust the dose.

Expert medical opinion is necessary for the administration of this medicine in the elderly:

- who have a greater tendency for constipation, dizziness or drowsiness;
- who have problems with the prostate.

If any of these take to you, warn your doctor before taking this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription.

Tell your doctor if you are taking any of the following medicines:

- Other central nervous system depressors

Morphine derivatives (analgesics, cough medicines); benzodiazepines; barbiturates; other anxiolytics besides benzodiazepines; hypnotics; neuroleptics; sedative antidepressors; central antihypertensives; Baclofen; thalidomide.

When taken simultaneously, the central depressive effect increases. Reduced awareness can make it dangerous to drive and / or operate machinery.

- Atropine and other atropine substances (imipramine antidepressants, anti-Parkinsonian, anticholinergics, antispasmodics atropine, disopyramide, phenothiazine neuroleptics).

When taken simultaneously, they can cause additional side effects of atropine: urinary retention, constipation, dry mouth.

Taking food and drink with RODAVAN N tablets

This medicine can cause drowsiness, which is increased by alcohol consumption: refrain from alcoholic beverages or medicinal products containing alcohol during treatment with this medicine.

Pregnancy and breastfeeding

If you are pregnant or are breastfeeding, think you may be pregnant or planning to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Take this medicine during pregnancy only after doctor's advice.

If during treatment you find out that you are pregnant, consult your doctor, because only he can assess the need for further therapy.

In the last trimester of pregnancy, excessive use of this medicine can cause adverse effects on the infant. Therefore, it is necessary to always seek the opinion of a doctor before taking this medicine and never take more than the recommended dose.

Breastfeeding

Because this medicine passes into breast milk, its use is not recommended during breastfeeding period.

Driving and using machines

Trigonik, medicine with possible impact on the psychophysical capacities (warning when driving a car and using machines).

Sleepiness and reduced awareness related to the use of this medicine can be pronounced and dangerous, especially when driving and operating machinery. This phenomenon is more pronounced if they are consumed with alcoholic drinks or medicines containing alcohol, which should thus be avoided.

Other warnings

The medicine contains the sugar lactose. In case of intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE RODAVAN N

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Instructions for administration of the medicine

The medicine is administered orally.

Swallow the tablet with a glass of water.

For children aged 2-6 years, due to the risk of strangulation, crush the tablets before administration.

Dosage

The medicine is intended for adults and children over 2 years.

Adults and children over 12 years

Take 1 to 2 tablets 30 minutes before the planned trip. If necessary, the dose may be repeated at intervals of every 6 hours. Do not take more than 6 tablets per day.

Children from 6 to 12 years

Take ½ to 1 tablet 30 minutes before the planned trip. If necessary, the dose may be repeated at intervals of every 6 hours. Do not take more than 3 tablets per day.

Children from 2 to 6 years

Take ¼ to ½ tablet 30 minutes before the planned trip. If necessary, the dose may be repeated at intervals of every 6 hours. Do not take more than 1½ tablet per day.

If you take more RODAVAN N than you should

If you take more medicine than you should, contact your doctor or pharmacist. If you get sick or lose consciousness, due to excessive absorption of the medicine, call your doctor immediately.

If you forget to take RODAVAN N

Do not take a double dose to make up for the forgotten tablet.

If you miss a dose, take the next dose at the usual time and continue to use the medicine as instructed by a doctor.

If you stop taking RODAVAN N

Take this medicine for as long as your doctor has prescribed.

If you suddenly stop using this medicine, no side effects are expected.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, RODAVAN N can cause side effects, although not everybody gets them.

Some side effects require you to interrupt treatment immediately and inform your doctor.

- Allergic reactions:

- the changes on the skin (erythema, eczema, redness, hives);

- the Quincke edema (urticaria with sudden swelling of the face and neck, which can lead to shortness of breath);

- anaphylactic shock.

- A significant drop in the number of white blood cells may be manifested as the emergence or strengthening of fever with signs of infection or without them.
- A significant drop in the number of blood platelets, which can be manifested by bleeding from the nose or gums.

There may be other side effects, such as:

- Drowsiness, reduction of attention;
- The weakening of memory or concentration, dizziness (more common in the elderly), balance disorder;
- Motor incoordination, tremors;
- Confusion, hallucinations;
- Dry mouth, blurred vision, urinary retention, constipation, palpitations, low blood pressure;
- Rarely anxiety, nervousness, insomnia;
- Very rarely may appear unusual movements of the head and neck in children.

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 RODAVAN N

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use RODAVAN N after the expiry date which is stated on the label.

Shelf life: 2 years.

6. FURTHER INFORMATION

What RODAVAN N contains

One tablet contains:

Dimenhydrinate 50.00 mg

RODAVAN N tablets contain the following ingredients: DC lactose, microcrystalline cellulose PH112, croscarmellose sodium, copovidone, magnesium stearate, colloidal silicon dioxide.

What RODAVAN N looks like and contents of the pack

RODAVAN N tablets are white to off-white, round with the division line on one side.

RODAVAN N tablets are packed in a box with 10 tablets.

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

Bosnalijek d.d.

Jukićeva 53, Sarajevo, BiH