

PACKAGE LEAFLET: INFORMATION FOR THE USER

AVIOMARIN

50 mg tablets

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 Aviomarin tablets are and what it is used for
2. Before you use Aviomarin tablets
3. How to use Aviomarin tablets
4. Possible side effects
5. How to store Aviomarin tablets
6. Further information

1. WHAT AVIOMARIN TABLETS ARE AND WHAT ARE THEY USED FOR

- Aviomarin 50 mg tablets belong to a group of medicines called: Preparations acting on respiratory system; Antihistamines for systemic use; Aminoalkyl ethers.

Aviomarin 50 mg tablets are used for:

- The prevention and treatment of nausea, vomiting and / or dizziness associated with motion sickness.
- The prevention and treatment of nausea and vomiting caused by other factors (except in the cases of taking chemotherapeutic agents for the treatment of cancer).

2. BEFORE YOU USE AVIOMARIN TABLETS

Do not use Aviomarin tablets

- if you have hypersensitivity to dimenhydrinate or any of the other ingredients;
- In the case of an acute asthmatic attack;
- In the case of narrow angle glaucoma;
- If you have pheochromocytoma;
- In the case of porphyria

- If you have prostate hypertrophy;
- If you have convulsions (epilepsy, eclampsia);
- Children younger than 5 years.

Take special care with Aviomarin tablets

Although Aviomarin 50 mg tablets suit most people, some people should take it with caution. Caution is necessary in patients with narrowing of the pylorus (part of the stomach at the turn of the small intestine), liver disorders, Cardiac dysrhythmia, bradycardia, hypertension, chronic breathing disorder, asthma, low serum concentration of potassium and magnesium.

Particular caution is recommended in patients with congenital long QT syndrome or other clinically significant cardiac disorders (coronary heart disease, circulatory disorders, arrhythmias) and in those receiving concomitant medications that prolong the QT interval or cause hypokalemia.

Using other medicines

- Before you start taking Aviomarin tablets tell your doctor if you use any of the following medications:
- That which act on the central nervous system (antipsychotics, hypnotics, sedatives, anesthetics, analgesics; anticholinergic drugs such as atropine, biperiden, tricyclic antidepressants;) because concomitant use may lead to the strengthening of the effects of these drugs. It is particularly important not to use simultaneously antidepressants from the group of monoamine oxidase inhibitors (MAOIs), which can cause paralytic ileus (intestinal paralysis) that is life threatening, urinary retention and elevated intraocular pressure.
- That which prolong the QT interval, which is evident from the ECG (eg, antibiotics, neuroleptics, antiarrhythmic drugs, antimalarials).
- Which lead to hypokalemia (low concentration of potassium in the blood), such as specific diuretics - drugs that stimulate the kidneys to secrete salt, and in that way the liquid from organism and normalizing blood pressure.
- antihypertensive agents (medicines to treat high blood pressure), because they can lead to enhanced fatigue and increased antihypertensive effects.

Aviomarin tablets could cover the results of allergy tests.

Furthermore, it is necessary to take into account that Aviomarin tablets may mask potential ototoxic effects (Effects harmful to the ear) of drugs from the group of aminoglycoside drugs (composition for the treatment of a bacterial infection).

Alcohol should be avoided during the application of Aviomarin tablets because of possible changes or the intensity of the effect of dimenhydrinate (active drug substance). This can lower the ability to drive or operate machinery.

Pregnancy and breast-feeding

- Ask your doctor, health care provider or pharmacist for advice before taking any medicine.

Dimenhydrinate should not be used in the final weeks of pregnancy because it can lead to premature uterine contractions. The drug can be applied during the first 6 months only if other non-pharmacological measures have not yielded the desired results.

Dimenhydrinate is excreted in breast milk. Until now there were no adverse effects on infants.

If there are signs of irritation in infants, it is necessary to consider discontinuation of the drug usage interruption of breastfeeding.

Driving and using machines

- Since Aviomarin tablets lower psychomotor skills, the drug should not be taken by the people who drive or use machinery.

3. HOW TO USE AVIOMARIN TABLETS

- Always take use Aviomarin tablets exactly as your doctor or health care provider has told you. You should check with your doctor, health care provider or pharmacist if you are not sure. The usual dose is:

Prevention

At least 30 minutes before the planned trip or application of a drug which is poorly tolerated:

- Adults and children over 14 years: 50 to 100 mg (1-2 tablets)
- Children aged 5 to 14 years: 25 mg to 50 mg (½ - 1 tablet).

If necessary, dose can be taken again, at interval of every 4-6 hours.

Nausea and vomiting

- Adults and children over 14 years: 50 to 100 mg (1-2 tablets) every 4 to 6 hours if necessary, but not more than 400 mg per day. Children aged 5 to 14 years: 25 mg to 50 mg (½-1 tablet) every 6 to 8 hours if necessary, but not more than 150 mg per day.

In the elderly, medicament is to be administered in the lowest recommended dose for adults since they are sensitive to the anticholinergic drug effects. Treatment should be as short as possible.

The drug may be taken independently of the food intake. The tablets should be swallowed with sufficient fluid (eg, water).

If you use more Aviomarin tablets than you should

- If you take more Aviomarin tablets than you should, immediately tell your doctor or pharmacist! If possible, bring your medication and this leaflet.
- First symptoms of overdose appear 30 minutes to 2 hours after taking toxic doses (25 mg / kg body weight) and consist mostly of headaches and dizziness, fatigue and progressive intoxication.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Aviomarin tablets can cause side effects, although not everybody gets them. If you notice any side effects, please inform your doctor or pharmacist about it.

Side effects according to frequency can be classified as:

Very often in more than 1 in 10 users

Often, in 1 to 10 users in 100 users

Uncommon: 1 to 10 in 1,000 users

Rare: 1 to 10 in 10 000 users

Very rare: in less than 1 in 10 000 users

Unknown: frequency cannot be estimated from the available data

Cardiac disorders

Rare: tachycardia.

Blood and lymphatic system disorders

Unknown: disorders of blood cells

Nervous system disorders

Very common: extreme tiredness, drowsiness, dizziness.

Eye disorders

Common: visual disturbances, increased intraocular pressure.

Respiratory, thoracic and mediastinal disorders

Often: Nose congestion

Gastrointestinal disorders

Common: nausea, vomiting, abdominal pain, constipation, diarrhea, dry mouth.

Renal and urinary system

Common: micturition disorders.

Skin and subcutaneous tissue disorders

Not known: allergic skin reactions, photosensitivity.

Musculoskeletal and connective tissue disorders

Very common: muscle weakness

General disorders and administration site reactions

Common: paradoxical drug reactions, shivering.

Hepatobiliary disorders

Not known: impaired liver function, cholestatic jaundice.

Psychiatric disorders

Common: mood changes, anxiety, insomnia, anxiety

Unknown: sleep disturbances after you suddenly stop using the medicine, of the drug addiction.

If you notice any side effects, please tell your doctor or pharmacist. This includes the any possible side effects not listed in this leaflet.

5. HOW TO STORE AVIOMARIN TABLETS

- Keep out of the reach and sight of children.
- Do not use this medicine after the expiry date which is stated on the label.
- Do not store above 25 °C. Store in the original carton
- 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. FURTHER INFORMATION

What Aviomarin tablets contain

- Active ingredients: dimenhydrinate.
- Other ingredients: microcrystalline cellulose; talk; silica, colloidal anhydrous; magnesium, stearate.
- One Aviomarin 50mg tablet contains 50 mg of dimenhydrinate.

Packing

- Aviomarin 50 mg tablets are white, round and biconvex, have smooth surface, with incised labeled "A" on one side of the tablet. Aviomarin 50 mg tablets are available in packs of 3 or 5 tablets in blisters.

The regime of dispensing

The drug is issued on prescription.

Manufacturer

PLIVA Croatia Ltd.

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