

Package leaflet: Information for the user

Cinfamar 50 mg coated tablets dimenhydrinate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in this leaflet

1. What Cinfamar is and what it is used for
2. What you need to know before you take Cinfamar
3. How to take Cinfamar
4. Possible side effects
5. How to store Cinfamar
6. Contents of the pack and other information

1. What Cinfamar is and what it is used for

Dimenhydrinate is the active substance of this medicine and it acts against travel sickness.

It is indicated for the prevention and treatment of the symptoms of travel sickness (land, air or sea) such as nausea, vomiting and/or dizziness for adults and children over 12 years of age.

You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

2. What you need to know before you take Cinfamar

Do not take Cinfamar

- If you are allergic to dimenhydrinate, diphenhydramine or any of the other ingredients of this medicine (listed in section 6).
- If you suffer from porphyria (a rare disorder, generally hereditary, in which a large quantity of porphyrin is eliminated in the stools and urine).
- If you suffer from asthma attacks.

Warnings and precautions

Talk to your doctor or pharmacist before taking Cinfamar.

- If you suffer from asthma, serious respiratory illnesses (chronic obstructive pulmonary disease, emphysema, chronic bronchitis), as it can cause a thickening of secretions and alter expectoration.
- If you suffer from a disease which causes an abnormal increase in the activity of the thyroid gland (hyperthyroidism) or increased intraocular pressure (glaucoma), or if you have an enlarged prostate (prostatic hypertrophy), hypertension or any disease that causes an obstruction of the urinary tract or of the gastrointestinal tract.
- If you suffer from seizures that include convulsive movements, with or without loss of consciousness (epilepsy).
- If you are over the age of 65 years, it may cause a dry mouth, urine retention, nausea, sedation, confusion and low blood pressure (hypotension).
- If you are using any medicine that causes toxicity in the ear, as it may mask symptoms of these toxic effects, such as whistling in the ears, dizziness or vertigo.

- Talk to your doctor before taking this medicine if you suffer from any disease or disorder of the liver or kidneys, stomach or duodenal ulcer, or inflammation of the stomach (gastritis).
- Talk to your doctor before taking this medicine if you suffer from or have suffered from heart disease or disorders (cardiac arrhythmia, myocardial ischaemia).
- If you suspect that you may have symptoms of appendicitis such as nausea, vomiting or stomach cramps, you should visit a doctor to rule out the presence of appendicitis, as dimenhydrinate may hinder the diagnosis of this illness.
- It is advisable to avoid exposure to very high temperatures and follow suitable hygiene and dietary measures, such as appropriate aeration and hydration.
- Avoid exposure to the sun (even if it is cloudy) and ultraviolet lamps (UVA rays) while taking this medicine.

Children

This medicine must not be used in children under 2 years of age.

Other medicines and Cinfamar

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, if you are using any of the following medicines it may be necessary to modify the dose of Cinfamar or not use it:

- Anaesthetics and other substances that depress the central nervous system.
- Antibiotics of the aminoglycoside group.
- Antidepressants such as monoamine oxidase inhibitors (MAOIs).
- Anti-Parkinson's drugs.
- Neuroleptics (used to calm agitation and neuromuscular hyperactivity).
- Ototoxic medicines (that can affect the ear). (See the section Warnings and Precautions).
- Medicines that can cause photosensitivity (skin reactions due to sensitivity to sunlight).

Interaction with diagnostic tests

If you are going to have any allergy tests, including cutaneous tests (of the skin) suspending the treatment 72 hours before starting the test is recommended, to avoid altering the results of the test.

Cinfamar with food, drink and alcohol

No alcohol should be consumed while taking with this medicine.
It is advisable to take this medicine with food or with milk.

Pregnancy and breast-feeding

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 use of medicines during pregnancy can be dangerous for the embryo or foetus and must be monitored by your doctor.

As this medicine passes into breast milk, breast-feeding mothers should not use this medicine without having spoken to their doctor or pharmacist first.

Driving and using machines

Do not drive or operate dangerous machinery as this medicine causes drowsiness or a reduced ability to react at the recommended doses.

Cinfamar contains sodium

This medicine contains less than 23 mg (1 mmol) of sodium per tablet; it is essentially “sodium-free”.

3. How to take Cinfamar

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.

The recommended doses are:

- Adults and children over 12 years of age: 1 or 2 tablets (50 - 100 mg of dimenhydrinate) per dose. If necessary, it may be administered every 4-6 hours. Do not administer more than 8 tablets (400 mg of dimenhydrinate) per day, spread over several doses.
- Children aged 2 to 12 years: This medicine is not suitable for children aged from 2 to 12 years old. Other forms of this medicine may be more suitable for children between the ages of 2 and 12 years, such as Cinfamar children 25 mg coated tablets or Cinfamar children 12.5 mg oral solution.
- Children under 2 years of age: Do not administer to children under 2 years old.
- Patients with liver diseases: consult your doctor before taking this medicine, as it may be necessary to reduce the dose.

This medicine is taken orally.

Taking the first dose at least half an hour before starting the journey (preferably 1-2 hours before) is recommended and, if you have not taken it before, take the first dose when symptoms appear. If sickness persists, wait at least 4 to 6 hours between one dose and the next.

It is advisable to take the tablets with food, water or milk to minimise gastric irritation. You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

If you take more Cinfamar than you should

If you have taken more Cinfamar than you should, consult your doctor or pharmacist immediately.

The symptoms due to overdose principally include: dilated pupils, reddened face, excitation, hallucinations, confusion, irritation of the stomach and intestines with nausea, vomiting and diarrhoea, alterations in movement, seizures, deep state of loss of consciousness (coma), sudden reduction in respiratory and heart functions (cardiorespiratory arrest) and death. The symptoms can take more than 2 hours from overdose to appear.

In case of overdose or accidental ingestion, tell your doctor or pharmacist immediately, indicating the medicine and quantity ingested.

4. Possible side effects

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

The adverse reactions are usually mild and transient, above all at the start of the treatment.

During the period of use of dimenhydrinate, the following adverse reactions have been reported, though their frequency has not been clearly established:

- Nausea, vomiting, constipation, diarrhoea, stomach ache.
- Lack of appetite and dry mouth.
- Sleepiness and sedation (drowsiness).
- Headache, vertigo, dizziness.
- Increases of viscosity of mucous in the bronchi, hindering breathing.
- Urine retention and sexual impotence.
- Glaucoma (increased pressure in the eyes).
- Dilated pupils, blurred or double vision.
- Allergic reactions in the skin and sensitivity to sunlight, after intense exposure. Urticaria, itching and reddening of the skin may appear.
- Reduction of the number of red cells, white cells, leukocytes and platelets in the blood.

- Porphyria (a rare disorder, generally hereditary, in which a large quantity of porphyrin is eliminated in the stools and urine).
- Hypertension or hypotension (increase or reduction of blood pressure).
- Tachycardia, palpitations and/or cardiac arrhythmias.
- It can cause hyperexcitability, above all in children, with symptoms such as insomnia, nervousness, confusion, tremor, irritability, euphoria, delirium, palpitations and even seizures.

Reporting of 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cinfamar

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

Do not store at temperatures above 25°C.

Do not use this medicine after the expiry date which is stated on the box and label 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 Cinfamar contains

- Each tablet contains 50 mg of dimenhydrinate as the active substance.
- The other ingredients are:
 - *Core: calcium hydrogen phosphate dihydrate*, maize starch, microcrystalline cellulose, sodium carboxymethyl starch (type A) (from potato) povidone, talc, magnesium stearate.
 - *Coating: Hypromellose 606, hypromellose 615, macrogol 6000, deionised water.*

What Cinfamar looks like and contents of the pack

White, cylindrical, biconvex coated tablets, scored on one side.

It is supplied in packs containing 4 or 10 coated tablets.

Marketing Authorisation Holder and Manufacturer

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