

## Package leaflet: Information for the user

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

#### **1. What cinfammar is and what it is used for**

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

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

#### **2. What you need to know before you take cinfammar**

##### **Do not use cinfammar:**

- If you are allergic to dimenhydrinate, diphenhydramine or to 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**

- 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 an elderly patient, it may cause a dry mouth, urine retention, glaucoma, 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, etc.).
- 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.

### **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.

### **Children**

Do not give this medicine to 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:

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

### **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.

## **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 again if you are not sure.

The recommended doses are:

- Adults and children over 12 years of age: 1-2 tablets (50 to 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 7 to 12: This medicine is not suitable for children aged from 2 to 12 years old. Other form(s) 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 hours between one dose and the next.

It is advisable to take this medicine with food, water or milk to minimise gastric irritation.

If the symptoms worsen or if they persist after 7 days, you must talk to your doctor.

#### **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, 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, go immediately to a medical centre or call the Toxicology Information Service (telephone: +0034 91 562 0420), indicating the medicine and quantity ingested.

#### **4. Possible side effects**

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

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

- Tachycardia, palpitations and/or cardiac arrhythmias.
- Reduction of the number of red cells, white cells, leukocytes and platelets in the blood.
- Sleepiness and sedation (drowsiness).
- Headache, vertigo, dizziness.
- It can cause hyperexcitability, above all in children, with symptoms such as insomnia, nervousness, confusion, tremor, irritability, euphoria, delirium, palpitations and even seizures.
- Glaucoma (increased pressure in the eyes), dilated pupils, blurred or double vision.
- Increases of viscosity of mucous in the bronchi, hindering breathing.
- Nausea, vomiting, constipation, diarrhoea, stomach ache, lack of appetite and dry mouth.
- Urine retention and sexual impotence.
- Allergic reactions in the skin and sensitivity to sunlight, after intense exposure. Urticaria, itching and reddening of the skin may appear.
- 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).

#### **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.

No special storage conditions are required.

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 dispose of any medicines via wastewater or household waste. Ask your pharmacist how to dispose of 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 (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 Licence Holder and Manufacturer**

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