

**Package leaflet: Information for the user**

**cinfamar caffeine 50 mg/50 mg coated tablets**  
dimenhydrinate/caffeine

**Read all of this leaflet carefully before you start taking this medicine, as 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 cinfamar caffeine is and what it is used for.
2. What you need to know before you take cinfamar caffeine.
3. How to take cinfamar caffeine.
4. Possible side effects.
5. How to store cinfamar caffeine.
6. Contents of the pack and other information.

**1. What cinfamar caffeine is and what it is used for**

cinfamar caffeine is a medicine containing two active substances: dimenhydrinate and caffeine. Dimenhydrinate acts against travel sickness. Caffeine exerts a stimulating effect upon the nervous system, countering the drowsiness which dimenhydrinate may cause.

cinfamar caffeine is 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 cinfamar caffeine**

**Do not take cinfamar caffeine:**

- If you are allergic (hypersensitive) to dimenhydrinate, diphenhydramine, caffeine (or its derivatives such as aminophylline, theophylline, etc.) 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.
- If you suffer from mental disorders that provoke nervous excitation or seizures that include convulsive movements, with or without loss of consciousness (epilepsy).
- If you suffer from states of anxiety or insomnia (difficulty sleeping).
- If you suffer from serious disorders of the liver or heart.
- If you suffer from a stomach or duodenal ulcer.
- If you suffer from arterial hypertension.

## Warnings and precautions

Talk to your doctor or pharmacist before taking cinfamar caffeine. In particular, ask him/her if you suffer or have previously suffered any of the following:

- If you suffer from asthma, serious respiratory illnesses (chronic obstructive pulmonary disease, emphysema, chronic bronchitis), as it can cause a thickening of secretions that can 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) or any disease that causes an obstruction of the urinary tract or of the gastrointestinal tract.
- 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.
- If you are diabetic, you must take into account that caffeine can raise blood sugar levels.
- 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.), especially when you engage in physical exercise or are in high altitude areas.
- If you are sensitive to caffeine or other xanthines, such as theophylline, aminophylline or others, you must talk to your doctor before taking this medicine.
- 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.
- The simultaneous use of tobacco and the caffeine contained in this medicine can increase the degradation of the caffeine, so you may feel drowsy.

## Children

Do not give this medicine to children under 12 years of age.

## Other medicines and cinfamar caffeine

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

This is particularly important if you are using the following medicines, as it may be necessary to modify the dose of cinfamar caffeine or stop taking it:

Medicines that interfere principally with **dimenhydrinate**:

- 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: medicines 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).

Medicines that interfere principally with **caffeine**:

- Oral contraceptives.
- Anti-infectious agents in the quinolone group (for example: piperimidic acid, ciprofloxacin), linezolid and erythromycin.
- Barbiturates: used as anticonvulsants.
- Adrenergic bronchodilators and theophylline: used to combat bronchial asthma.
- Calcium.
- Cimetidine: used for the treatment of excess gastric secretion and stomach ulcer.
- Disulfiram: used in treatment of chronic alcoholism.
- Phenytoin: used to treat epilepsy.
- Iron: used to treat anaemia. Caffeine reduces the absorption of iron, they must be taken at least 2 hours apart.
- Lithium: antidepressant.
- Mexiletine: used for irregular heartbeats (cardiac arrhythmias).
- Procarbazine: anticancer agent.
- Selegiline: used to treat Parkinson's disease.
- Thyroxine: used to treat thyroid disorders.

### **Interferences with diagnostic tests**

If you are to undergo any tests (blood, urine or other tests), tell your doctor that you are taking this medicine, because it may alter the results of such 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.

In addition, diabetic patients must take into account that caffeine can increase blood glucose levels.

### **Interactions with food, drink and alcohol**

No alcohol should be consumed while taking with this medicine.

Limit your intake of drinks that contain caffeine (coffee, tea, chocolate and cola drinks) while taking this medicine.

### **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 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.

Breast-feeding women should talk to their doctor or pharmacist before using this medicine.

### **Driving and using machines**

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

### **3. How to take cinfamar caffeine**

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

The recommended dose in adults and adolescents over 12 years of age is 1 or 2 tablets per dose (50-100 mg of dimenhydrinate and 50-100 mg of caffeine). If necessary, it may be administered every 4-6 to hours.

Do not take more than 8 tablets a day (corresponding to 400 mg of dimenhydrinate and 400 mg of caffeine).

#### **Use in children**

Children under 12 years of age must not take this medicine.

**Patients with liver diseases:** talk to your doctor before taking this medicine, as it may be necessary to adjust the dose.

cinfamar caffeine is administered orally. Taking the first dose at least half an hour before starting a journey (preferably 1-2 hours before) with at least 4 hours between one dose and the next is recommended. It is advisable to take the tablets with food, water or milk to minimise gastric irritation.

Do not take the last dose in the 6 hours prior to going to bed, to avoid possible insomnia, above all in patients with difficulty sleeping.

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

#### **If you take more cinfamar caffeine than you should**

If you have taken more cinfamar caffeine 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 intake, go immediately to a medical centre or call the Toxicology Information Service, specifying the medication and the amount taken.

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

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

Like all medicines, cinfamar caffeine 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.

While using this medicine, the following side effects 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 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.

In addition, because it contains caffeine, the following may appear:

- Excitation, shaking and/or difficulty sleeping.
- Humming in the ears.
- Disorientation.
- Accelerated respiration.
- Hot flushes.
- Abundant excretion of urine.
- Hyperglycaemia or hypoglycaemia (increase or reduction of blood glucose).

### **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 caffeine**

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

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the container after the abbreviation: 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 caffeine contains**

- Each tablet contains 50 milligrams of dimenhydrinate and 50 milligrams of caffeine as active ingredients.
- The other ingredients are:
  - Core: maize starch, colloidal anhydrous silica, microcrystalline cellulose, calcium hydrogen phosphate dihydrate, magnesium stearate, sodium carboxymethyl starch type A (from potato), povidone, talc.

- Coating: macrogol 6000, hypromellose 606 and hypromellose 615.

**What cinfamar caffeine looks like and contents of the pack**

**cinfamar caffeine** are 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:**

Laboratorios Cinfa, S.A.

C/ Olaz-Chipi, 10 - Polígono Industrial Areta

31620 Huarte - Pamplona (Navarre). Spain.

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