

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 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

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1. What Cinfamar Caffeine is and what it is used for

Cinfamar Caffeine is a medicine containing two active substances: dimenhydrinate and caffeine. Dimenhydrinate is an active substance that it acts against travel sickness.

Caffeine exerts a stimulating effect upon the nervous system, countering the drowsiness which dimenhydrinate may cause.

Cinfamar Caffeine is an medicine that is indicated for the prevention and treatment of the symptoms of travel sickness (land, air or sea) manifested 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 Caffeine

Do no take Cinfamar Caffeine

- If you are allergic 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.

- If you are allergic to any medications to treat allergies, you may also be allergic to dimenhydrinate.
- If you suffer from asthma or 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) 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.

Children

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

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 you may not be able to take 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 (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: piperidic 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, so 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, etc.), 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.

Cinfamar Caffeine 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 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.

Breast-feeding

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

While being treated with this medicine, do not drive or operate dangerous machinery as this medicine causes drowsiness or a reduced ability to react at the recommended doses.

Cinfamar Caffeine 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 Caffeine

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 dose is:

Adults and children over 12 years of age

1 or 2 tablets per dose. If necessary, it may be administered every 4 - 6 hours.

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

Patients with liver diseases

Talk to your doctor before taking this medicine, as it may be necessary to adjust the dose.

Use in children

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

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.

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 Caffeine than you should

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

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.

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

4. Possible side effects

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

The side effects usually occur at the beginning of 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).
- Hypotension (reduced 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, due to the caffeine, the following effects may occur:

- 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 at temperatures above 25°C.

Do not use this medicine after the expiry date which is stated on the container 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 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) (type A), 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.

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