

CARIBAN 10 MG / 10 MG

Modified release hard capsules

Doxylamine succinate / Pyridoxine hydrochloride

Please read all this leaflet carefully before you start taking this medicine 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 symptoms 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. See section 4.

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1. What is Cariban and what it is used for

This medicine belongs to the group of anti-emetics and anti-nausea medicines and is indicated for the symptomatic treatment of nausea and vomiting during pregnancy in adults.

Cariban contains two medicines ('active substances') called: 'doxylamine succinate' and 'pyridoxine hydrochloride'. Doxylamine succinate belongs to a group of medicines called 'antihistamines'. Pyridoxine hydrochloride is another name for "Vitamin B6"

2. What you need to know before you take Cariban

Do not take Cariban:

- If you are allergic to doxylamine, pyridoxine or any of the other ingredients in this medicine listed in Section 6.
- If you are hypersensitive to antihistamines (allergy medications) derived from ethanolamine (such as diphenhydramine or carbinoxamine)
- If you are taking antidepressants such as monoamine oxidase inhibitors (MAOIS) as Cariban may intensify and extend the side effects on the nervous system.
- If you are taking strong CYP450 isoenzyme inhibitors.
- If you suffer from porphyria (a rare metabolic disorder).
- If you have hereditary problems with fructose intolerance, poor absorption of glucose-galactose or sucrase-isomaltase deficiency.
- If you are vomiting for any other reason.

Warnings and precautions

Ask your doctor or pharmacist for advice before taking Cariban.

You must consult a doctor before taking this medicine if you suffer from:

- Glaucoma (increased pressure on the eyes)
- If you suffer from a peptic ulcer (break in the lining of the stomach or first part of the intestine with narrowing of the digestive tract), pyloroduodenal obstruction (difficulty passing food from the stomach to the intestine) or obstruction in the neck of the bladder (urinary tract disease), urinary obstruction (difficulty urinating);
- Thyroid disorder.
- Heart disease and high blood pressure, as Cariban can aggravate the disease
- Prolonged QT interval syndrome (heart disease);
- Asthma and other respiratory disorders, such as chronic bronchitis (persistent inflammation of the bronchi) and pulmonary emphysema (disease which affects the lungs making breathing difficult) or chronic obstructive pulmonary disease (COPD), as Cariban can aggravate the disease.
- Kidney and/or liver diseases.
- Epilepsy, as it can aggravate the disease.
- Low levels of potassium in the blood or other electrolytic changes.

Cariban can increase sensitivity to light, therefore it is not recommended to sunbathe during treatment.

Cariban may mask symptoms that can affect your ears (such as dizziness), so you should consult your doctor if you are taking other medicines that might have the same effects.

Be aware of any signs of abuse or dependence on this treatment. If you have any substance use disorders (alcohol, medication or other), talk to your doctor.

Cariban contains pyridoxine hydrochloride (vitamin B6), therefore additional levels from diet and vitamin B6 supplements should be assessed.

Cariban can increase dehydration and cause heat stroke due to decreased perspiration. You may feel sleepy after taking Cariban. If this happens do not do other activities that need your full attention - unless your doctor tells you it is ok to do so.

Children and adolescent

There is no data available on the safety and efficiency of Cariban in children under 18 years of age.

Other Medicines and Cariban

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

Cariban must not be taken concomitantly with the following medicines:

- Anticholinergics such as medicines for treating depression or Parkinson's disease, monoamine oxidase inhibitors or MAOIS (treatment for depression), antipsychotics (medicines for treating mental disorders), atropine medicines for the treatment of spasms or disopyramide (for the treatment of certain heart problems), as it may increase toxicity.
- central nervous system depressants (for example barbiturates, hypnotics, sedatives, anxiolytics, opioid type analgesics, antipsychotics, procarbazine or sodium oxibate).
- Antihypertensive drugs (medicines for controlling blood pressure) with effects on the central nervous system such as guanabenz, clonidine or alpha-methyldopa.
- If you are taking other medicines that cause toxicity on the ear, such as carboplatin or cisplatin (medicines for treating cancer), chloroquine (medicine for treating or preventing malaria) and other antibiotics (medicines for treating infections) such as erythromycin or intravenous aminoglycosides, among others, as Cariban can mask the toxic effects of these medicines, so you should have periodic check ups on your ears.
- Medicines that reduce the elimination of other medicines such as derivatives of azole or macrolides, as these can increase the effects of Cariban.
- Some diuretics (medicines that increase the elimination of urine).
- Medicines with an action on the heart such as those used to treat arrhythmias (irregular heartbeat), some antibiotics, certain malarial drugs, certain antihistamines, certain medicines used to reduce lipids (fat) in the blood or certain neuroleptics (medicines used to treat mental disorders).
- Medicines that produce a photosensitive reaction (increased reaction of the skin when exposed to sunlight) such as some antiarrhythmics (amiodarone, quinidine), some antibiotics (tetracyclines, fluoroquinolones, azithromycin, erythromycin, among others), some antidepressants (imipramine, doxepin, amitriptyline), some antifungal medicines (griseofulvin), antihistamines (promethazine, chlorpheniramine, diphenhydramine, among others), some anti-inflammatories (piroxicam, naproxen, among others), some anti-viral drugs (amantadine, ganciclovir), some diuretics (furosemide, chlorothiazide), as these can cause additional photosensitive effects.
- Levodopa, as the pyridoxine in Cariban can reduce its effect.
- Medicines for treating epilepsy (phenobarbital, phenytoin) as pyridoxine can reduce their levels in the blood.
- Medicines such as hydroxyzine, isoniazid or penicillamine as, when combined with pyridoxine, they could cause vitamin B6 deficiency.

Interactions with diagnostic tests

This medicine may alter the following analytical tests: false negative in skin tests in which allergenic extracts are used (allergy tests). You should stop taking this medicine several days before taking the test.

Taking Cariban with food, drink, and alcohol

It may take longer for Cariban to take effect when the capsules are taken with food. You should avoid drinking alcohol while taking Cariban as this can increase the toxicity of the medicine. See Section 3 How to take Cariban.

Pregnancy, breastfeeding, and fertility

Cariban is intended for use in pregnant women.

Cariban is not recommended if you are breastfeeding.

Driving and using machinery:

Cariban may cause drowsiness in some patients, so you should avoid situations that require you to be alert, such as driving vehicles or handling machinery, at least during the first few days of treatment until you know how it affects you.

Cariban contains sucrose

This medicine contains sucrose. If your doctor has told you that you are intolerant to certain sugars, consult your doctor before taking this medicine.

3. How to take Cariban

Always take Cariban exactly as recommended by your doctor. Check with your doctor if you are not sure.

The recommended dose is 2 capsules at bedtime if the nausea and vomiting occur in the morning (Day 1). If this dose allows you to control your symptoms, continue taking two capsules. However, if symptoms persist into the afternoon of Day 2, the patient should continue the usual dose of two capsules at bedtime (Day 2) and on Day 3 take three capsules (one capsule in the morning and two capsules at bedtime). If these three capsules do not adequately control symptoms on Day 3, the patient can take four capsules starting on Day 4 (one capsule in the morning, one capsule mid-afternoon and two capsules at bedtime).

The maximum daily dose is 4 capsules (one in the morning, another in middle of the afternoon and two at bedtime).

The capsules must be swallowed whole, without chewing and on an empty stomach, with a sufficient amount of liquid, preferably water.

Use in children and adolescents:

The safety and efficacy of Cariban have not been established in children under 18 years of age.

If you take more Cariban than you should

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

Symptoms of possible intoxications could be neurological alterations such as agitation, hallucinations, or intermittent seizures which, in extreme cases, might lead to a reduction in vital activity and result in coma. If any of these symptoms occur, you will be given the appropriate treatment.

If you forget to take Cariban

If you forget to take a dose of Cariban, take it as soon as possible. However, if it is nearly time for the next dose, skip the forgotten dose and continue with the normal dosage. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, Cariban can cause side effects, although not everybody gets them. Cariban side effects are in general mild and transient but are more common in the first few days of treatment.

Common side effects (can affect up to 1 in every 10 people): drowsiness and effects such as a dry mouth, constipation, blurred vision, urinary retention or increased bronchial secretion.

Uncommon side effects (can affect up to 1 in every 100 people): asthenia (weakness), peripheral oedema (swelling in the arms and legs), nausea, vomiting, diarrhea, skin rash, tinnitus (ringing in the ears), orthostatic hypotension (head rush due to changes in posture), diplopia (double vision), glaucoma, confusion or photosensitivity reactions.

Rare side effects (can affect up to 1 in every 1,000 people): restlessness, trembling, convulsions, or blood problems such as haemolytic anaemia.

Other side effects whose frequency is not known (frequency cannot be estimated from the available data): tachycardia (faster heart rate (heartbeats)), vertigo or dyspnea.

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 Cariban

Store below 25°C

Keep this medicine out of sight and reach of children.

Do not use this medicine after the expiry date stated on the container. The expiry date is the last day of the month shown.

Medicines should not be disposed of via wastewater or household waste. Ask your

pharmacist how to dispose of any packaging and medicines you no longer require. These measures will help to protect the environment.

6. Contents of the pack and additional information

What Cariban contains

The active ingredients are Doxylamine succinate 10 mg and Pyridoxine hydrochloride 10 mg.

The other ingredients are:

- The capsules contain: sucrose, corn starch, shellac, povidone, talc, methacrylic acid -methyl methacrylate copolymer and anhydrous colloidal silica.
- The capsule is composed of gelatin, indigo carmine (E132), quinoline yellow (E104) and titanium dioxide (E171).

What Cariban looks like and contents of the pack

Cariban is supplied in boxes containing 24 green capsules in two PVC/PVdC-aluminium blisters, of 12 capsules in each.

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