

Patient Information Leaflet
Casacol Expectorant Syrup
Methoxyphenamine Hydrochloride, 20mg/5ml
Guaiphenesin, 100mg/5ml
Sodium Citrate, 200mg/5ml

Read all of this leaflet carefully because it contains important information for you. This medicine is available without prescription. Nevertheless you still need to use CASACOL carefully to get the best results from it.

- Keep this leaflet you may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 5 days.

In this leaflet

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1. WHAT IS CASACOL AND WHAT IT IS USED FOR

The name of your medicine is CASACOL Expectorant Syrup.

The active substances are Methoxyphenamine Hydrochloride 20mg, Guaiphenesin 100mg and Sodium Citrate 200mg per 5ml syrup. The other ingredients are Propylene Glycol, Saccharin Sodium, Ethyl- (E214), Propyl- (E216), and Methyl- (E218) hydroxybenzoate, Linctus flavour, Ponceau 4R (E124), Sorbitol (E420) and Purified Water.

CASACOL is a sugar-free syrup.

CASACOL Expectorant Syrup is an expectorant and decongestant. It liquefies tenacious mucous and facilitates easier breathing. CASACOL is used to treat cough and congestion associated with the common cold, bronchitis, etc.

2. BEFORE YOU TAKE CASACOL

To make sure it is safe for you to take CASACOL, please read the following section carefully. If you are receiving medication, or are under a doctor's care, consult him before using CASACOL.

Do not take CASACOL

- If you are suffering from impaired renal function.
- If you are suffering from a disease called porphyria.
- If you are hypersensitive (allergic) to Methoxyphenamine, Guaiphenesin or Sodium Citrate, or any other ingredient of CASACOL.
- If you are suffering from coronary thrombosis (blood clots in the heart), high blood pressure, hyperactive thyroid (overactive thyroid gland leading to various symptoms including racing heart, sweating, nervousness, shakiness and sleep interruptions), closed-angle glaucoma (eye condition of the optic nerve that may lead to progressive sight loss) or urinary retention (inability to empty the bladder).
- If you are already taking a type of Medicine called Monoamine Oxidase Inhibitors (certain medicines used for treatment of Depression or Parkinsons Disease), or within 10 days of stopping such treatment. If you are unsure whether you are taking these medicines, check with your doctor or pharmacist.
- If you are currently receiving other sympathomimetic drugs such as Pseudoephedrine, Phenylephrine, Dopamine or Noradrenaline.

- If you are taking any other cough and cold medicine.
- Casacol should not be used in children under the age of 6 years.

Take special care with CASACOL

- If you have heart disease or are taking medication for heart failure, you should only use CASACOL under the direct supervision of a doctor.
- If you are receiving digitalis therapy (digoxin).
- Casacol contains sorbitol, if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- The colouring agent Ponceau 4R(E124), may cause allergic reactions.
- Ethyl- (E214), Propyl- (E216), and Methyl- (E218) hydroxybenzoate may cause allergic reactions (possibly delayed) and exceptionally, bronchospasm (a sudden constriction of the muscles on the walls of the airways in the lungs leading to wheeze, cough and shortness of breath).
- Casacol Expectorant Syrup may cause increased difficulty in emptying the bladder for people with prostatic hypertrophy (enlargement of the prostate gland).

Pregnancy and Breast Feeding

CASACOL should not be used by pregnant or breast-feeding women except under the direct supervision of a doctor.

Driving or using machines

CASACOL does not normally produce any effects on ability to drive or use machines.

Taking other medicines

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

The following medicines may cause a rise in blood pressure if taken with Casacol Expectorant Syrup. Please consult your Doctor or Pharmacist before taking Casacol Expectorant Syrup if you are currently taking any of these medicines:

- Decongestants (medicines for coughs and colds).
- Tricyclic Anti Depressants (used to treat depression).
- Appetite suppressants and amphetamine like psychostimulants (drugs used to treat a wide range of conditions such as severe depression, attention deficit hyperactivity disorder (ADHD), smoking cessation).
- Nicotine contained in nicotine replacement therapies and in tobacco products
- Monoamine Oxidase Inhibitors (MAOI) (drugs used to treat psychiatric conditions or used to treat Parkinson's Disease (which affects a person's motor skills))

Casacol Expectorant Syrup should only be used with caution if used with the following medicines:

- Digitalis Therapy (Medicines used to treat heart disorders)
- Beta-Adrenergic Blockers (used for high blood pressure and heart problems)
- Guanethidine (used for high blood pressure)
- Reserpine (used for high blood pressure and certain psychiatric conditions)
- Methyldopa (used for high blood pressure)
- and any other medicines used to treat high blood pressure

If used with certain anaesthetic agents called halogenated anesthetics, Casacol Expectorant Syrup may cause, or worsen, ventricular arrhythmias (irregular heart rhythms that originate in the lower chambers of the heart).

3. HOW TO TAKE CASACOL

Always take CASACOL exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. The normal dose for CASACOL is as follows:

Adults: One or two 5ml spoonfuls 3 to 4 times daily.

Children: 6 to 12 years; One 5ml spoonful 3 to 4 times daily. (Maximum daily dose: 20ml syrup)

The dose should be measured using the spoon enclosed with this pack. The spoon lets you choose either the 2.5ml or 5ml quantity.

Treatment should not be continued for longer than 5 days. If symptoms persist, consult your doctor. Not more than 4 doses should be given in any 24 hours. Do not exceed the stated dose. Consult your doctor, a pharmacist or other healthcare professional before use in children between 6 and 12 years.

If you forget to take a dose:

Do not take a double dose to make up for forgotten individual doses.

If you take more CASACOL than you should:

If you or someone else have accidentally taken more syrup than you should, talk to your doctor or pharmacist immediately or go to your nearest hospital casualty department. Take this leaflet with you if you still have it.

4. POSSIBLE SIDE EFFECTS

Like all medicines CASACOL can have side effects. Some people may experience urinary retention (inability to empty the bladder), gastric discomfort, redness of the skin or may have difficulty sleeping or feel restless while taking CASACOL. Uncontrolled shaking (tremor) or fits (convulsions) may occur. May cause allergic reactions (possibly delayed). If you experience any undesirable effect while taking this medicine you should stop taking it and consult your doctor or pharmacist if the symptoms are severe or persistent.

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. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of the medicine.

5. STORING CASACOL

Keep out of reach and sight of children.

Do not store above 25°C.

Do not refrigerate or freeze.

6. FURTHER INFORMATION

What Casacol looks like and contents of pack.

Casacol is a syrup, a pale red straw coloured liquid with a faint odour of cherry, contained in an amber glass bottle.

Casacol is available in 125 ml and 300 ml bottles.

A spoon with a 2.5ml and 5ml measure is supplied with all packs of this product.

Product Authorisation Holder:

Phoenix Labs, Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, Co. Meath, Ireland.

Manufacturer responsible for batch release:

Laboratórios Basi - Indústria Farmacêutica, S.A.

Parque Industrial Manuel Lourenço Ferreira, Lotes 15 e 16, 3450-232 Mortágua
Portugal

Do not use CASACOL after the expiry date printed on the carton and on the side of the label.

Date of preparation of leaflet: November 2025 PA1113/007/001