

Carbosten Syrup Leaflet

Leaflet Size: A6

CARBOSTEN® SYRUP (CARBOCISTEINE 5% SYRUP)

Composition:

Each 5ml of the syrup contains: Carbocisteine 250mg.

Pharmacology: Carbocisteine is a mucolytic agent which decreases the viscosity of the mucus, fluidizes it and facilitates its evacuation, thus promoting recovery. As a mucoregulatory agent, it helps regenerate the impaired bronchial mucosa.

Pharmacokinetics: Carbocisteine is rapidly and well absorbed from the gastrointestinal tract with peak plasma concentrations occurring 90 to 120 minutes after an oral dose. It appears to penetrate into lung tissue and respiratory mucus. Carbocisteine is excreted in the urine as unchanged drug and metabolites. Acetylation, decarboxylation, and sulfoxidation have been identified as the major metabolic pathways. Sulfoxidation may be governed by genetic polymorphism.

Indications: Carbocisteine is a mucolytic agent for the adjunctive therapy of respiratory tract disorders characterized by excessive, viscous mucus, including chronic obstructive airways disease.

Posology and method of administration:

Method of administration: *For oral use.*

Dosage:

For use in Adults only (Over 15 years).

Usual dose: 15ml three times daily initially using the measuring cup provided, which can be reduced to 10ml when a satisfactory response has been obtained.

Contraindications: Hypersensitivity to the active substance(s) or to any of the excipients and it's also contra- indicated in patients with active peptic ulceration. Carbocisteine should not be used with antitussives (cough suppressants) or medicines that dry up bronchial secretions

Special warnings and precautions for use: Caution is recommended in the elderly, in those with a history of gastro-duodenal ulcers, or those taking concomitant medications known to cause gastrointestinal bleeding. If gastrointestinal bleeding occurs, patients should discontinue medication.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Interaction with other medicinal products and other forms of interaction: None stated.

Use in Pregnancy: Although tests in mammalian species have revealed no teratogenic effects, Carbosten is not recommended during the first trimester of pregnancy.

Use in Lactation: Effects not known

Effects on ability to drive and use machines: None.

Undesirable effects: The most common adverse effects includes anaphylactic reactions, fixed drug eruption, gastrointestinal bleeding, vomiting, skin rashes and allergic skin eruptions. Isolated cases of bullous dermatitis such as Stevens-Johnson syndrome and erythema multiforme have also been reported.

Overdose: Gastric lavage may be beneficial, followed by observation.

Gastrointestinal disturbance is the most likely symptom of Carbosten overdose.

Treatment is purely symptomatic.

Presentation: 100ml or 125ml in amber coloured glass and PET bottle with measuring cup in a unit box.

Storage: Store in a dry place, below 30°C, protected from light. Keep out of reach of children.

Shelf life: 3 years (36 months) from the date of manufacture.

Manufactured By:



**DAWA Limited, Plot No. 7879/8, Baba Dogo Road, Ruaraka
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