

• BỘ Y TẾ SOLMUX BRONCHO  
**CỤC QUẢN LÝ DƯỢC HỖN DỊCH**  
**ĐÃ PHÊ ĐUYỀN**  
Hộp 1 chai 60 mL

Lần đầu: 42/08/2049



# Solmux® BRONCHO

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Pediatric Suspension

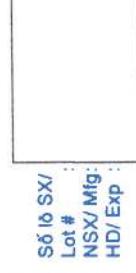
Hỗn dịch dành cho trẻ em

SEK:

Rx Thuốc ban theo đơn

Hộp 1 chai

SEK:

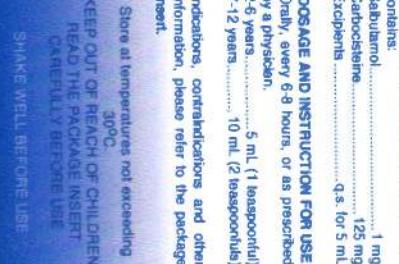
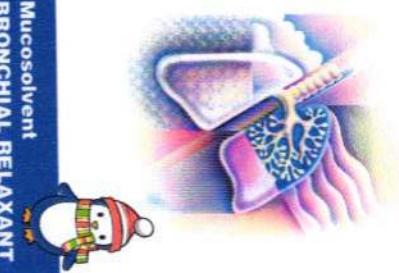


**COMPOSITION**  
Each 5 mL (1 teaspoonful) suspension  
contains:  
Salsalate..... 1 mg  
Carbocisteine..... 125 mg  
Excipients..... q.s. for 5 mL

**DOSAGE AND INSTRUCTION FOR USE**  
Orally, every 6-8 hours, or as prescribed  
by a physician.  
5 mL (1 teaspoonful)  
7-12 years..... 10 mL (2 teaspoonfuls)

Indications, contraindications, and other  
information, please refer to the package  
insert.

Store at temperatures not exceeding  
30°C.  
KEEP OUT OF REACH OF CHILDREN  
READ THE PACKAGE INSERT  
CAREFULLY BEFORE USE  
SHAKE WELL BEFORE USE



Mucosolvent  
BRONCHIAL RELAXANT

Registered trademark of Westmont  
Pharmaceuticals, Inc.

Manufactured by/  
WHO-GMP, GLP, GSP  
No. 16 VSP II, Street No. 7, Vietnam Singapore II  
Industrial Park, Hoa Phu Ward, Thu Dau Mot City,  
Binh Duong Province, Vietnam





Rx Prescription medicine

## Solmux® Broncho

Pediatric Suspension  
MUCOSOLVENT – BRONCHIAL RELAXANT

### COMPOSITION

Each 5 mL (1 teaspoonful) suspension contains :  
Salbutamol..... 1 mg  
Carbocisteine..... 125 mg  
Excipients: Agar, Carboxymethylcellulose Sodium, Sorbitol Solution, Glycerin, Sodium Benzoate, Sodium Hydroxide, FD&C Yellow # 6, Saccharin Sodium, Juicy Orange Flavour.

### RATIONALE OF THE COMBINATION

Asthma and chronic bronchitis are associated with airway hyperresponsiveness and mucus plugging. Treatment of these diseases, therefore, should include a bronchodilator to alleviate bronchospasm and to improve mucociliary transport, and a mucolytic to lessen the viscosity of excessive, thick, viscid mucus from the airway thereby facilitating the removal of abnormal secretions from the lungs.

This combination is rational for the management of patients with asthma and chronic bronchitis. The bronchodilation and improved mucociliary transport brought about by salbutamol is complementary to the action of carbocisteine in loosening abnormal mucus secretion and facilitating expectoration. Salbutamol and carbocisteine also share a compatible dosing schedule.

### PHARMACODYNAMICS

Carbocisteine, a derivative of cysteine, is a mucolytic agent. It corrects the intracellular abnormalities of glycoprotein synthesis resulting in increased secretion of less viscous sialomucin and sulfoglycopptides, and reduction of the highly viscous fucosin content. Carbocisteine normalizes the secretory functions of the mucosal epithelium and improves mucus flow from surface epithelial cells and subepithelial mucus glands. Salbutamol stimulates adenylyl cyclase which catalyzes cyclic-3',5'-adenosine monophosphate from ATP. The cAMP thus formed mediates cellular responses such as relaxation of the bronchial smooth muscle.

### PHARMACOKINETICS

Carbocisteine is rapidly and well-absorbed after oral administration. Peak serum concentrations are reached in 1-2 hours. Plasma half-life is 1.5 to 2 hours. Carbocisteine penetrates well into lung tissues and respiratory mucus, suggesting local action. Carbocisteine undergoes acetylation, decarboxylation, and sulfoxidation. Majority of the drug is excreted unchanged in the urine.

After oral administration of salbutamol, the most part passes through the liver and then into the blood and the absolute bioavailability is about 40%. Maximal plasma concentrations are reached 2-3 hours after the ingestion. Only 5% of the drug is bound to the plasma proteins. The half-life is 5-6 hours. About 50% is metabolized as inactive sulfocomjugates, 75-80% is excreted in the urine as active and inactive forms.

### INDICATIONS

For the symptomatic treatment of productive cough associated with acute and chronic obstructive airways disease, like acute and chronic bronchitis, bronchial asthma and bronchiectasis.

### DOSAGE AND INSTRUCTION FOR USE

Orally, every 6 – 8 hours, or, as prescribed by a physician.

2 - 6 years..... 5 mL (1 teaspoonful)  
7-12 years..... 10 mL (2 teaspoonfuls)

### CONTRAINDICATIONS

Known hypersensitivity to any of the components of the product. Children under 2 years old.

### PRECAUTIONS

Consult a doctor if :

- ♦ The cough persists for more than 3 weeks or if it gets worse.
- ♦ The cough is accompanied by a recurring fever.
- ♦ You experience upset stomach or heartburn after taking this product.
- ♦ You have any new or unusual symptoms.

Effects on ability to drive and use machines: none.

Pregnancy and lactation: The effects of Solmux® Broncho when used during pregnancy or lactation are not known. Therefore, administer with caution to women during these periods.

### SIDE-EFFECTS

Solmux® Broncho is generally well-tolerated. Adverse effects of carbocisteine are rare and include skin rashes, nausea, headaches, myalgia, dizziness and urinary incontinence. Gastrointestinal disturbance often occurs with acute overdosage. Salbutamol may cause tremor, palpitation, tachycardia. These effects are less observed in children. Tachycardia and digestive disturbance (nausea, vomiting) caused by high doses of salbutamol have been reported.

Please Inform the doctor of all undesirable effects upon drug administration.

### OVERDOSE AND TREATMENT

The symptoms of salbutamol overdosage may include malaise, headache, dizziness, nausea, nervousness, limb tremor, tachycardia, cardiac arrhythmia, blood pressure change, convulsion. Hypokalaemia also may occur. Treatment consists of discontinuation of oral salbutamol together with appropriate symptomatic therapy. In the event of serious poisoning, the stomach should be emptied and, if necessary, a beta-blocker administered with caution in patients with a history of bronchospasm.

### DRUG INTERACTIONS

Concomitant administration with carbocisteine enhances the absorption of sodium amoxicillin. Pretreatment with cimetidine severely impairs the urinary elimination of carbocisteine sulfoxides. Concomitant intake of diuretics may enhance the hypokalaemia that occurs with large doses of salbutamol. The effects of this drug are inhibited by beta-blockers. Salbutamol may increase blood glucose in patients using antidiabetic medicine.

### PRESENTATION

Box of 60 mL bottle.

### STORAGE

Store at temperatures not exceeding 30°C.

### SHELF-LIFE

24 months from manufacturing date.

### USE UPON DOCTOR'S PRESCRIPTION ONLY

KEEP OUT OF REACH OF CHILDREN

READ THE PACKAGE INSERT CAREFULLY BEFORE USE

FOR MORE INFORMATION, PLEASE ASK FOR DOCTOR'S ADVICE

Manufactured by :

UNITED INTERNATIONAL PHARMA CO., LTD.

WHO-GMP, GLP, GSP

No.16 VSIP II, Street No.7, Vietnam-Singapore II Industrial Park

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