

Rx

**SALBUTAMOL AS SULFATE
BROMHEXINE HCl
GUAIFENESIN**

COFNIL

2mg/4mg/100mg Per 10ml Syrup

Bronchodilator/ Mucolytic/ Expectorant

FORMULATION:

Each 10ml contains:

Salbutamol (as Sulfate) BP	2mg
Bromhexine Hydrochloride BP	4mg
Guaifenesin USP	100mg

PRODUCT DESCRIPTION:

COFNIL is orange-coloured syrup with odor of orange flavor.

INDICATIONS:

Relief of productive & wheezing cough associated with bronchitis, pneumonia, asthma and other respiratory infections.

PHARMACOLOGY:

COFNIL Syrup through rational combination offers effective and fast relief in various Broncho-Pulmonary Disorders.

Bromhexine acts on the mucus at the formative stages in the glands, within the mucus-secreting cells. Bromhexine disrupts the structure of acid mucopolysaccharide fibers in mucoid sputum and produces a less viscous mucus, which is easier to expectorate.

Salbutamol is a selective β_2 -adrenoceptor stimulant that causes the relaxation of the smooth muscles through the increase of the intracellular cyclic adenosine monophosphate (cAMP): bronchial and uterine muscles are relaxed, the peripheral vessels are dilated, heart rate increases, and there are metabolic effects (e.g. decrease of the plasma potassium levels).

Guaifenesin is thought to act as an expectorant by increasing the volume and reducing the viscosity of secretions in the trachea and bronchi. Thus, it may increase the efficiency of the cough reflex and facilitate removal of the secretions.

PHARMACOKINETICS:

Bromhexine hydrochloride is rapidly absorbed from the gastrointestinal tract and undergoes extensive first-pass metabolism in the liver. Its oral bioavailability is stated to be only about 20%. It is widely distributed to body tissues and is highly bound to plasma proteins. About 85 to 90% of a dose is excreted in the urine mainly as metabolites. It has a terminal elimination half-life of up to about 12 hours.

Bromhexine crosses the blood brain barrier and small amounts cross the placenta.

Salbutamol is absorbed from the gastrointestinal tract and undergoes considerable first-pass metabolism to the phenolic sulphate. Both unchanged drug and conjugate are excreted primarily in the urine. The bioavailability of orally administered salbutamol is about 50%.

Guaifenesin

Absorption: Readily absorbed from gastrointestinal tract.

Plasma half life: Plasma half life is 1 hour.
Elimination: Renal, as inactive metabolites

DOSAGE:

Adults: 10ml (2 teaspoonfuls)
Children 6-12 years: 5 ml-10ml (1-2 teaspoonfuls)
Children below 6 years: 5 ml (1 teaspoonful) Taken three times a day with food (Take 1 hour before or 2 hours after meals) or as prescribed by the physician.

Caution: For infants and children up to 6 years, use according to advice of the Medical Practitioner.

PRECAUTIONS:

COFNIL Syrup should be used with caution in patients of hyperthyroidism, diabetes mellitus, serious cardiovascular disorders, hypertension and peptic ulcers.

ADVERSE DRUG REACTIONS:

These are generally mild and rare. Skeletal muscle tremor particularly of the hands, palpitations and muscle cramps are seen occasionally. Slight tachycardia, headache and peripheral vasodilation have been reported after large doses.

REPORTING OF SUSPECTED ADVERSE REACTIONS:

To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reactions is necessary. Healthcare professionals are encouraged to report any suspected adverse reaction/s directly to the importer/distributor and/or to FDA: www.fda.gov.ph Patients are advised to seek immediate medical attention at the first sign/s of adverse reactions.

USE IN PREGNANCY AND LACTATION :

During pregnancy and lactation the product may be used only if recommended by a registered medical practitioner.

OVERDOSE AND TREATMENT:

In the case of overdose/aggravated symptoms, appropriate monitoring and management of the patient should be implemented.

CAUTIONS:

FOODS, DRUGS, DEVICES and COSMETICS ACT prohibit dispensing without prescription.

STORAGE:

Store at temperatures not exceeding 30°C. Protect from light & heat.
Keep out of the reach of children.
For Oral use only.

PRESENTATION AND PACKAGING:

COFNIL Syrup is available in Amber Bottle x 60ml. (Box of 1's)

FDA Registration Number: DRP-4624
Date of Renewal Authorization: 01 February 2022
Date of Revision of Package Insert: 16 March 2022

AW203014
010201891



Manufactured by:
Pharmatec Pakistan (Pvt.) Ltd.,
D-86/A, S.I.T.E., Karachi-Pakistan.

Imported and Distributed by:
SAHAR INTERNATIONAL TRADING, INC.
354, Aguirre Ave., Phase III, BF Homes,
Paranaque City, Philippines.
<http://www.saharpharma.com>