℞Bromhexine, Terbutaline and Guaiphenesin Expectorant
Broncorex® Expectorant

1. GENERIC NAME

Bromhexine, Terbutaline and Guaiphenesin Expectorant

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Bromhexine Hydrochloride I.P.	4 mg
Terbutaline Sulphate I.P.	1.25 mg
Guaiphenesin I.P.	50 mg

Contains Carmoisine and Sunset Yellow FCF as colourants
Saccharin Sodium I.P. and Sorbitol Solution I.P. (70% Non Crystallising) (as artificial sweetners)

3. DOSAGE FORM AND STRENGTH

Dosage form - Expectorant
Refer section 2 for strength

4. CLINICAL PARTICULARS

4.1 Therapeutic indication

Broncorex is indicated in the treatment of productive cough when associated with bronchospasm in conditions such as bronchitis, bronchial asthma, chronic obstructive pulmonary disease (COPD), bronchiectasis, and emphysema.

4.2 Posology and method of administration

Broncorex expectorant is usually given 3 times a day in the following doses:

Adults: 2 teaspoons (10 ml)

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Children:	6-12 years:	1-1½ teaspoons	(5-7.5 ml)
	2-6 years:	½-1 teaspoon	(2.5-5-ml)

4.3 Contraindications

Patients with a history of hypersensitivity to sympathetic amines and any other components in the expectorant.

4.4 Special warnings and precautions for use

While treating cough as a symptom, it is important to make every effort to determine and treat appropriately the underlying cause, such as a specific infection.

Caution should be observed while prescribing Broncorex to patients with hypertension, cardiovascular disease (including arrhythmias, coronary insufficiency), uncontrolled diabetes mellitus, and patients with hyperthyroidism, history of seizures, or in patients who are unusually responsive to sympathomimetic amines.

Patients susceptible to hypokalemia should be monitored because transient early falls in serum potassium levels have been reported with β agonists.

Since mucolytics, such as bromhexine, may disrupt the gastric mucosal barrier, bromhexine should be used with care in patients with a history of peptic ulceration.

Hypersensitivity and skin reactions, including severe cutaneous adverse reactions, have been reported with bromhexine or ambroxol. If hypersensitivity or severe skin reactions are experienced, discontinue treatment immediately

4.5 Drugs interactions

Adverse metabolic effects of high dose β_2 agonists such as terbutaline may be exacerbated by concomitant administration of high doses of corticosteroids. Patients should therefore be monitored carefully when two forms of therapy are used together. Hypokalemia with high doses of β_2 agonists may result in increased susceptibility to digitalis induced cardiac arrhythmias. Hypokalemia may be enhanced by concomitant administration of aminophylline or other xanthines, corticosteroids or by diuretic therapy.

Terbutaline reduces serum theophylline concentrations by increasing its systemic clearance. This may or may not have clinical implications, as improved clinical scores have still occurred with combined therapy despite the theophylline concentration being lower than when used alone. If respiratory symptoms persist, an increase in dosage may be contemplated while monitoring theophylline side-effects and concentration.

Other sympathomimetic bronchodilators or epinephrine should not be used concomitantly with terbutaline sulfate, since their combined effect on the cardiovascular system may be deleterious to the patient. This recommendation does not preclude the judicious use of an aerosol bronchodilator of the adrenergic stimulant type in patients receiving Broncorex.

Terbutaline sulphate should be administered with caution in patients being treated with monoamine oxidase (MAO) inhibitors or tricyclic antidepressants, since the action of terbutaline sulfate on the vascular system may be potentiated.

Furazolidone has significant MAO inhibiting activity and should not be used concurrently with sympathomimetics.

β-adrenergic receptor blocking agents not only block the pulmonary effect of terbutaline, but may produce severe asthmatic attacks in asthmatic patients. Therefore, patients requiring treatment for both bronchospastic disease and hypertension should be treated with medication other than β-adrenergic blocking agents for hypertension.

4.6 Use in special populations

Safety of Broncorex has not been studied in pregnancy and lactation. Therefore, probable benefits should be weighed against possible risks, before prescribing Broncorex during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

No special precautions are required.

4.8 Undesirable effects

Bromhexine: Gastrointestinal side effects may occur occasionally with bromhexine and a transient rise in serum aminotransferase values has been reported.

Guaiphenesin: Gastrointestinal discomfort has occasionally been reported with guaiphenesin. Very large doses cause nausea and vomiting.

Terbutaline: The adverse reactions of terbutaline sulfate are similar to those of other sympathomimetic agents.

The most commonly observed side effects are tremor and nervousness. The frequency of these side effects appear to diminish with continued therapy. Other commonly reported reactions include increased heart rate, palpitations, and dizziness. Other reported reactions include headache, drowsiness, vomiting, nausea, sweating, muscle cramps, hypersensitivity, rash, shortness of breath, chest discomfort, weakness, anxiety and dry mouth. These reactions are generally transient and usually do not require treatment.

There have been rare reports of elevations in liver enzymes and of hypersensitivity vasculitis.

4.9 Overdose

Though reports are not available, exaggerated pharmacological effects of the individual ingredients may occur, e.g., overdose of β_2 agonists such as terbutaline may lead to significant drop in blood pressure due to peripheral vasodilatation.

5. PHARMACOLOGICAL PROPERTIES

5.1 Mechanism of Action

Bromhexine is a mucolytic agent. (For details please refer to section 5.2)
Bromhexine hydrochloride is a mucolytic agent, which liquifies thick, tenacious sputum. Viscosity of sputum is reduced by dissolving mucopolysaccharide fibres. It also improves mucocilliary clearance of secretions.

Guaiphenesin is an expectorant. It increases the output of sputum and bronchial secretions by reducing adhesiveness and surface tension. By increasing the volume of bronchial secretions, it reduces the viscosity of tenacious sputum. The increased flow of less viscid secretions also promotes ciliary action.

Terbutaline sulphate is a directly acting sympathomimetic agent with selective β_2 stimulant effect. β_2 agonists help alleviate bronchospasm associated with cough. Relief of bronchospasm facilitates drainage of accumulated secretions.

5.2 Pharmacodynamic properties

Tolerance, or tachyphylaxis, is a recognized effect of beta-adrenergic bronchodilator therapy. Receptor binding studies in small number of patients have shown a decrease in receptor binding sites (between 40% - 53%) after terbutaline therapy.

5.3 Pharmacokinetic properties

Bromhexine hydrochloride is rapidly absorbed from the gastro-intestinal tract and about 85% to 90% of a dose is excreted in the urine, mainly as metabolites. One of these, ambroxol is pharmacologically active, with actions similar to the parent compound. Bromhexine is highly bound to plasma proteins.

Terbutaline sulphate is variably absorbed from the gastrointestinal tract and is subject to fairly extensive first pass metabolism. There are no known active metabolites. Terbutaline has half-life of 3-4 hours. It is excreted in the urine partly as inactive conjugates and partly as unchanged terbutaline.

Guaiphenesin is absorbed from the gastro-intestinal tract. It is metabolized and excreted in the urine.

6. NONCLINICAL PROPERTIES

6.1 Animal Toxicology and Pharmacology

No data available

7. DESCRIPTION

Broncorex is a bright, reddish, orange clear syrupy liquid, free from foreign contaminants.

8. PHARMACEUTICAL PARTICULARS

8.1 Incompatibilities

Not known

8.2 Shelf-life

24 months

8.3 Packaging information

30 ml (Amber glass bottles), 50 ml and 100 ml amber coloured PET bottles sealed with Aluminium ROPP caps.

8.4 Storage and handling instructions

Store below 25°C.
No specific handling Instruction.

9. Patient counseling information

Caution should be observed in patients with hypertension, cardiovascular disease (including arrhythmias, coronary insufficiency), uncontrolled diabetes mellitus, and patients with hyperthyroidism, history of seizures. Patients should also be advised that if they have any discomfort, medical advice should be sought without delay.

10. Details of manufacturer:

Manufactured by -

Pfizer Limited at Khata No. 845/713 and 1108/970/1, 34th KM, Tumkur Road, T – Begur, Nelamangala, Banglore Rural – 562 123

Marketed by -
Pfizer Limited, The Capital – A Wing, 1802, 18th Floor, Plot No. C-70, G Block, Bandra Kurla Complex, Bandra (East), Mumbai - 400 051, India

11. Details of permission or license number with date

Manufacturing License No. KTK/25A/719/2011 dated 08-Jun-2017

12. Date of revision

July 2021