PROFESSIONAL INFORMATION FOR

BRONCOL COUGH LINCTUS

SCHEDULING STATUS

S2

1 NAME OF THE MEDICINE

BRONCOL COUGH LINCTUS (30 mg/180 mg/100 mg syrup)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 mL syrup contains:

Dextromethorphan hydrobromide	30,0 mg
Ammonium chloride	180,0 mg
Panthenol	100,0 mg

Contains preservative:

Methyl hydroxybenzoate	0,10 % *m/v*

Contains sugar:

Sucrose	5,77 g

Contains sweetener:

Saccharine sodium	8,0 mg
Sodium cyclamate	5,0 mg

For the full list of excipients, see **section 6.1**

3 PHARMACEUTICAL FORM

Brown opaque syrup.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

BRONCOL COUGH LINCTUS is indicated for the relief of productive or non-productive bronchial cough in colds, bronchitis and other respiratory tract disorders.

4.2 Posology and method of administration

Posology

Adults:	10 mL two to four times daily.
Children (6 to 12 years):	5 mL two to four times daily.

Method of administration

BRONCOL COUGH LINCTUS may be taken undiluted or diluted with water, milk, tea, fruit juices, etc., preferably after meals.

4.3 Contraindications

BRONCOL COUGH LINCTUS is contraindicated in:

- Patients with known hypersensitivity to dextromethorphan hydrobromide, ammonium chloride, panthenol or to any of the excipients used in the formulation of BRONCOL COUGH LINCTUS (see **section 6.1**).
- Children under the age of 6 years.
- Ammonium salts, as contained in BRONCOL COUGH LINCTUS, are contraindicated in patients with hepatic or renal impairment.
- Dexpanthenol, as contained in BRONCOL COUGH LINCTUS, is contraindicated in haemophiliacs and in patients with ileus due to mechanical obstruction.

- Dextromethorphan, as contained in BRONCOL COUGH LINCTUS, should not be given during an acute asthma attack and patients at risk of developing respiratory failure.
- Patients taking monoamine oxidase inhibitors (MAOIs), or for 2 weeks after stopping the MAOI medicine.
- Patients taking serotonin reuptake inhibitors.

4.4 Special warnings and precautions for use

- Dextromethorphan, as contained in BRONCOL COUGH LINCTUS, should not be given to patients at risk of developing respiratory failure. Caution is needed in patients with a history of asthma, and it should not be given during an acute attack (see **section 4.3**). Care is also advisable in patients with bronchitis, emphysema, or in other conditions where chronic or persistent cough occurs.
- BRONCOL COUGH LINCTUS contains 5,77 g sucrose per 10 mL. This should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take BRONCOL COUGH LINCTUS.
- BRONCOL COUGH LINCTUS contains methyl hydroxybenzoate which may cause allergic reactions (possibly delayed).
- Cases of dextromethorphan abuse and associated dependence have been reported. Caution with BRONCOL COUGH LINCTUS is particularly recommended for adolescents and young adults, as well as in patients with a history of drug abuse or use of psychoactive substances.
- Dextromethorphan, as contained in BRONCOL COUGH LINCTUS, is metabolised by hepatic cytochrome P450 2D6. The activity of this enzyme is genetically determined. About 10 % of the general population are poor metabolisers of CYP2D6. Poor

metabolisers and patients with concomitant use of CYP2D6 inhibitors may experience exaggerated and/or prolonged effects of dextromethorphan. Caution with BRONCOL COUGH LINCTUS should therefore be exercised in patients who are slow metabolisers of CYP2D6 or use CYP2D6 inhibitors (see **section 4.5**).

- If a patient is a known slow metaboliser of CYP2D6 or is using any other medicines (such as serotonergic medicines, including selective serotonin reuptake inhibitors (SSRIs – see **section 4.3**), medicines which impair the metabolism of serotonin (including MAOIs – see **section 4.3**) or CYP2D6 inhibitors, a doctor or pharmacist should be consulted prior to taking BRONCOL COUGH LINCTUS. Serotonergic effects, including the development of a potentially life-threatening serotonin syndrome, have been reported for dextromethorphan, with concomitant administration of medicines with serotonergic effects.
- There have been a few reports of allergic reactions possibly associated with dexpanthenol, as in BRONCOL COUGH LINCTUS.
- Smoking tobacco: Since BRONCOL COUGH LINCTUS decreases coughing, it makes it difficult to get rid of the mucus that may collect in the lungs and airways resulting from smoking.

4.5 Interaction with other medicines and other forms of interaction

BRONCOL COUGH LINCTUS is contraindicated in patients taking MAOIs, or for 2 weeks after stopping the MAOI (see **section 4.3**). Severe and sometimes fatal reactions have been reported after the use of dextromethorphan, as contained in BRONCOL COUGH LINCTUS, in patients receiving MAOIs (monoamine oxidase inhibitors). Taking BRONCOL COUGH LINCTUS when taking MAO inhibitors or having taken them within the past 2 to 3 weeks may cause coma, dizziness, excited or unusual behaviour, fever, high blood pressure, nausea, sluggishness, spasms, and tremors.

Dextromethorphan, as contained in BRONCOL COUGH LINCTUS, is primarily metabolised by the cytochrome P450 isoenzyme CYP2D6, the possibility of interactions with inhibitors of this enzyme, including amiodarone, haloperidol, propafenone, quinidine and thioridazine should be kept in mind.

Antiarrhythmics such as quinidine can increase serum concentrations of dextromethorphan, as contained in BRONCOL COUGH LINCTUS, markedly which may cause dextromethorphan toxicity in some patients.

Serotonin syndrome-like symptoms may occur when antibacterials such as linezolid are taken together with dextromethorphan, as contained in BRONCOL COUGH LINCTUS.

BRONCOL COUGH LINCTUS is contraindicated in patients taking selective serotonin reuptake inhibitors (see **section 4.3**). Adverse events such as hallucinations may occur when dextromethorphan, as contained in BRONCOL COUGH LINCTUS, is taken together with antidepressants such as fluoxetine. Serotonin-like symptoms may also occur when dextromethorphan, as contained in BRONCOL COUGH LINCTUS, is taken together with paroxetine.

4.6 Fertility, pregnancy and lactation

The safety of BRONCOL COUGH LINCTUS in fertility, pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

Dextromethorphan hydrobromide, as in BRONCOL COUGH LINCTUS, may cause somnolence and dizziness, which may impair the patient's ability to drive and use machines safely.

4.8 Undesirable effects

Dextromethorphan hydrobromide

Immune system disorders

Less frequent: Angioedema.

Psychiatric disorders

Less frequent: Insomnia.

Nervous system disorders

Less frequent: Dizziness, psychomotor hyperactivity, somnolence.

Gastrointestinal disorders

Less frequent: Gastrointestinal disturbances, abdominal pain, diarrhoea, nausea, vomiting.

Skin and subcutaneous tissue disorders

Less frequent: Pruritus, rash, urticaria.

Ammonium chloride

Gastrointestinal disorders

Frequency unknown: Nausea and vomiting.

Panthenol

Immune system disorders

Less frequent: Allergic reaction.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the “Adverse drug reaction and quality problem reporting form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problemreporting-form/ or to Cipla Medpro (Pty) Ltd.by email: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free).

4.9 Overdose

Dextromethorphan hydrobromide

Excitation, confusion and respiratory depression may occur after overdosage, including rare fatalities. Naloxone may be effective in reversing toxicity.

Ammonium chloride

Large doses of ammonium chloride may cause profound acidosis and hypokalaemia which should be treated symptomatically.

General

Clinical symptomatology may include one or more of the following: Tiredness, drowsiness, apathy, rigor, miosis and respiratory depression.

Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 10.1 Antitussives and expectorants

Dextromethorphan hydrobromide

Dextromethorphan hydrobromide is a cough suppressant. It is centrally acting with a direct action on the cough centre in the medulla. It may stop bronchial cough for up to 8 hours on a single dose.

Ammonium chloride

Ammonium chloride is used as an expectorant in productive cough. Ammonium chloride promotes the liquefaction of mucosal secretions and facilitates expectoration.

Dexpanthenol

Dexpanthenol has mild anti-inflammatory properties.

5.2 Pharmacokinetic properties

Dextromethorphan hydrobromide

Dextromethorphan hydrobromide is absorbed from the gastrointestinal tract. It is metabolised in the liver and excreted in the urine as unchanged dextromethorphan and demethylated metabolites including dextrorphan, which has some cough suppressant activity.

Ammonium chloride

Ammonium chloride is absorbed from the gastrointestinal tract. The ammonium ion is converted into urea in the liver. The anion is thus liberated into the blood and extracellular fluid. It causes a metabolic acidosis and decreases the pH of the urine. This is followed by transient diuresis.

Dexpanthenol

Dexpanthenol is absorbed from the gastrointestinal tract.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Caramel (Clark's caramel brown)

Invert syrup (containing methyl hydroxybenzoate, phosphoric acid 100 %, purified water, sodium carbonate, sucrose)

Liquorice essence R/7602

Purified water

Saccharine sodium

Sodium cyclamate

Spirit of anise.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precaution for storage

Store at or below 25 °C.

Protect from light.

6.5 Nature and contents of container

BRONCOL COUGH LINCTUS is packed in 100 mL or 200 mL medical round amber glass bottles with 28 mm Duet Wingard white plastic closures, with 10 mL snap-on measuring cup. The bottle is packed into a cardboard carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

CIPLA MEDPRO (PTY) LTD.

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Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

8 REGISTRATION NUMBER

G 0931 (Act 101/1965)

Namibia: NS1 Reg. No. 14/10.1/0567

9 DATE OF FIRST AUTHORISATION

18 March 2019

10 DATE OF REVISION OF THE TEXT

21 May 2024

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