PATIENT INFORMATION LEAFLET

BRONCOL COUGH LINCTUS

SCHEDULING STATUS: S2

BRONCOL COUGH LINCTUS (30 mg/180 mg/100 mg per 10 mL syrup)

Dextromethorphan hydrobromide 30 mg, ammonium chloride 180 mg and panthenol 100 mg

Contains sugar: sucrose 5,77 g/10 mL

Contains sweetener: saccharine sodium 8,00 mg/10 mL and sodium cyclamate 5,00 mg/10 mL

Read all of this leaflet carefully because it contains important information for you

BRONCOL COUGH LINCTUS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use BRONCOL COUGH LINCTUS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BRONCOL COUGH LINCTUS with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

1. What BRONCOL COUGH LINCTUS is and what it is used for

BRONCOL COUGH LINCTUS belongs to a group of medicines known as antitussives and expectorants. Antitussives are medicines which are used to supress coughing and expectorants are medicines that are used to clear mucus (phlegm) from your airways.

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

2. What you need to know before you take BRONCOL COUGH LINCTUS

Do not take BRONCOL COUGH LINCTUS:

- If you are hypersensitive (allergic) to dextromethorphan hydrobromide, ammonium chloride, panthenol or any of the other ingredients of BRONCOL COUGH LINCTUS (listed in **section 6**).
- If you have liver or kidney problems.
- If you are a haemophiliac (have a bleeding disorder in which the blood does not clot properly).
- If you have an obstruction in your gastrointestinal tract.
- If you are a child under the age of six (6) years.
- If you have asthma or if you are having an acute attack.
- If you are at risk of respiratory failure (a serious condition that makes it difficult to breathe on your own).
- If you are currently taking medicines which belong to a group called monoamine oxidase inhibitors (MAOIs), or if it is within 2 weeks since you stopped taking such a medicine.
- If you are currently taking medicines which belong to a group called serotonin reuptake

inhibitors.

Warnings and precautions

Special care should be taken with BRONCOL COUGH LINCTUS:

- If you have bronchitis, emphysema or any other condition where chronic or persistent cough occurs, please consult your doctor or pharmacist before taking BRONCOL COUGH LINCTUS.
- If you are an adult or adolescent with a history of drug abuse or use of psychoactive substances, as dextromethorphan contained in BRONCOL COUGH LINCTUS is associated with abuse and dependence.
- If you are a slow metaboliser of a specific enzyme in the body called CYP2D6 or if you are taking medicines which inhibit the CYP2D6 enzyme as this can result in exaggerated and/or prolonged effects of dextromethorphan, as contained in BRONCOL COUGH LINCTUS.
- If you experience signs of an allergic reaction, such as swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing, as allergic reactions have been reported with dexpanthenol, as in BRONCOL COUGH LINCTUS.
- If you are a smoker of tobacco. Since BRONCOL COUGH LINCTUS decreases coughing, it makes it difficult to get rid of the mucus (phlegm) that may collect in the lungs and airways resulting from smoking.

Other medicines and BRONCOL COUGH LINCTUS

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Severe and sometimes fatal reactions have been reported after the use of dextromethorphan,

as contained in BRONCOL COUGH LINCTUS, in patients receiving medicines known as monoamine oxidase inhibitors or having taken them within the past 2 to 3 weeks. These include coma, dizziness, excited or unusual behaviour, fever, high blood pressure, nausea, sluggishness, spasms and tremors.

Dextromethorphan, as contained in BRONCOL COUGH LINCTUS, may interact with medicines such as amiodarone, haloperidol, propafenone, quinidine, selective serotonin reuptake inhibitors and thioridazine. Tell your doctor or healthcare provider if you are taking any of these medicines.

Medicines known as antiarrhythmics (medicines that prevent and treat a heart rhythm that is too fast or irregular) such as quinidine can increase the concentration of dextromethorphan, as contained in BRONCOL COUGH LINCTUS, in your body which may cause dextromethorphan toxicity in some patients.

Serotonin syndrome-like symptoms (shivering, diarrhoea, fever, seizures etc.) may occur when antibacterials such as linezolid are taken together with dextromethorphan, as contained in BRONCOL COUGH LINCTUS.

Adverse events such as hallucinations may occur when dextromethorphan, as contained in BRONCOL COUGH LINCTUS, are taken together with antidepressants such as fluoxetine. Serotonin-like symptoms (shivering, diarrhoea, fever, seizures etc.) may also occur when dextromethorphan, as contained in BRONCOL COUGH LINCTUS, is taken together with paroxetine.

BRONCOL COUGH LINCTUS with food and drink

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

Pregnancy, breastfeeding and fertility

Safety in pregnancy, breastfeeding and fertility has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking BRONCOL COUGH LINCTUS.

Driving and using machines

Dextromethorphan, as contained in BRONCOL COUGH LINCTUS, may make you feel drowsy/sleepy or dizzy, which may impair your ability to drive and use machines.

It is not always possible to predict to what extent BRONCOL COUGH LINCTUS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which BRONCOL COUGH LINCTUS affects them.

BRONCOL COUGH LINCTUS contains sucrose and methyl hydroxybenzoate

BRONCOL COUGH LINCTUS contains 5,77 g of sucrose per 10 mL. This should be taken into account if you have diabetes mellitus.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking BRONCOL COUGH LINCTUS.

BRONCOL COUGH LINCTUS contains methyl hydroxybenzoate which may cause allergic reactions (possibly delayed).

3. How to take BRONCOL COUGH LINCTUS

Do not share medicines prescribed for you with any other person.

Always take BRONCOL COUGH LINCTUS exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you

are not sure.

The usual dose is:

Adults:	10 mL (2 medicine measures) two to four times daily.
Children (6 to 12 years):	5 mL (1 medicine measure) two to four times daily.

Your doctor will tell you how long your treatment with BRONCOL COUGH LINCTUS will last. If you have the impression that the effect of BRONCOL COUGH LINCTUS is too strong or too weak, tell your doctor or pharmacist.

If you take more BRONCOL COUGH LINCTUS than you should

Dextromethorphan, as contained in BRONCOL COUGH LINCTUS may cause excitation, confusion and respiratory depression after overdosage, including rare fatalities.

Large doses of ammonium chloride, as contained in BRONCOL COUGH LINCTUS, may cause profound acidosis (acid build up in the body) and hypokalaemia (low levels of potassium in the body).

Tiredness, drowsiness, unresponsiveness, a sudden feeling of cold with shivering accompanied by a rise in temperature, often with copious sweating, especially at the onset or height of a fever, constriction of the pupil, and difficult breathing are general symptoms of overdosage of BRONCOL COUGH LINCTUS.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take BRONCOL COUGH LINCTUS

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

BRONCOL COUGH LINCTUS can have side effects.

Not all side effects reported for BRONCOL COUGH LINCTUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BRONCOL COUGH LINCTUS, please consult your health care provider for advice.

If any of the following happens, stop taking BRONCOL COUGH LINCTUS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to BRONCOL COUGH LINCTUS. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Insomnia (difficulty sleeping).
- Dizziness.
- Drowsiness.
- Psychomotor hyperactivity (mood disorders e.g., pacing around the room, anxiety, tapping your toes etc.).
- Gastrointestinal disturbances.
- Stomach pain.
- Diarrhoea (loose stools).
- Nausea and vomiting.
- Urticaria (hives).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects 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 e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of BRONCOL COUGH LINCTUS.

5. How to store BRONCOL COUGH LINCTUS

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What BRONCOL COUGH LINCTUS contains

The active substances are dextromethorphan hydrobromide 30,0 mg, ammonium chloride 180,0 mg and panthenol 100,0 mg.

The other ingredients are 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 and spirit of anise.

What BRONCOL COUGH LINCTUS looks like and contents of the pack

BRONCOL COUGH LINCTUS is a brown opaque syrup.

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.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

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