PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

ADCO-LINCTOPENT SYRUP

Bromhexine hydrochloride 4 mg/5 ml and Orciprenaline sulphate 5 mg/5 ml

Contains Preservatives: Methyl parahydroxybenzoate 0,05 % m/v and

Propyl parahydroxybenzoate 0,01 % m/v

Alcohol free

Sugar free

Contains sweetener: Sorbitol 2500 mg

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

ADCO-LINCTOPENT SYRUP is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use ADCO-LINCTOPENT SYRUP carefully to get the best results from it.

- Keep this leaflet. You may need it to read it again.
- Do not share ADCO-LINCTOPENT SYRUP 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.

What is in this leaflet

1. What ADCO-LINCTOPENT SYRUP is and what it is used for
2. What you need to know before you take ADCO-LINCTOPENT SYRUP
3. How to take ADCO-LINCTOPENT SYRUP
4. Possible side effects
5. How to store ADCO-LINCTOPENT SYRUP
6. Contents of the pack and other information

1. What ADCO-LINCTOPENT SYRUP is and what it is used for

ADCO-LINCTOPENT SYRUP is a medicine acting on the lungs and consists of two active ingredients. Bromhexine hydrochloride thins the mucus making it easier to cough up, and Orciprenaline sulphate widens the airways making it easier to breath.

2. What you need to know before you take ADCO-LINCTOPENT SYRUP

Do not take ADCO-LINCTOPENT SYRUP

- if you are hypersensitive (allergic) to bromhexine hydrochloride or orciprenaline sulphate (active ingredients), or any of the other ingredients of ADCO-LINCTOPENT SYRUP (listed in section 6).
- if you have too much thyroid hormones in your blood.
- if you have an enlarged heart with an abnormal heartbeat.
- if you are taking monoamine oxidase inhibitors (MAOIs) which is a type of medication for depression or within 14 days of stopping such treatment.
- if you are pregnant or breastfeeding.

Warnings and precautions

Take special care when taking ADCO-LINCTOPENT SYRUP

- if you have a stomach ulcer.
- if you have asthma.
- if you have liver or kidney damage.
- If you are using other medicines to help relieve chest tightness, please consult your doctor
- if you are elderly.
- If you are using medicines affecting the heart, blood potassium levels need to be monitored
- If you have a cardiovascular disease i.e coronary heart disease, abnormal heart rhythms, or rapid heartbeats, blocked/narrowed arteries, hypertension, bulge in an artery, pheochromocytoma (rare tumour of the adrenal glands) or enlarged prostate.
- if you suffer from chest pain or discomfort.

- if you have high blood sugar (diabetes mellitus).
- if you have high pressure in your eye(s) (glaucoma).
- if you suffer from seizures.

Other medicines and ADCO-LINCTOPENT SYRUP

Always tell your health care provider if you are taking other medicines. (This includes all complementary or traditional medicines.) The following medicines are known to interact with ADCO-LINCTOPENT SYRUP.

- *sympathomimetic medicines* (class of compounds that mimic the effects of catecholamines, such as raising blood pressure and relieving nasal and bronchial congestion)
- *anticholinergics* (medicines which block acetylcholine and can help in the treatment of Parkinson's disease, allergies, insomnia, and nausea)
- *xanthine derivatives* (such as theophylline) (medicines used for their effects as mild stimulants and as bronchodilators)
- Certain medicines used to treat heart disease (*cardiac glycosides* and *quinidine*), and high blood pressure (*diuretics* and *beta-blockers*).
- *Inhaled anaesthetics*, before you have any surgery, tell the doctor that you are taking ADCO-LINCTOPENT SYRUP.
- Certain medicines used to treat depression (*monoamine oxidase inhibitors* and *tricyclic antidepressants*).
- Taking ADCO-LINCTOPENT SYRUP with corticosteroids may increase risks of low potassium levels, high blood sugar, and fluid in the lungs.

Pregnancy, breastfeeding and fertility

Safety in pregnancy and lactation has not been established. ADCO-LINCTOPENT SYRUP may inhibit uterine contractions in pregnancy. No fertility data available. 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 healthcare provider for advice before using this medicine.

Driving and using machines

ADCO-LINCTOPENT SYRUP may lead to drowsiness and impaired concentration that may be worsened by the simultaneous intake of alcohol or other central nervous system depressants. It is not always possible to predict to what extent ADCO-LINCTOPENT SYRUP may interfere with the daily activities of a patient. Patients should ensure that they do not engage in above activities until they are aware of the measure to which ADCO-LINCTOPENT SYRUP affects them.

ADCO-LINCTOPENT SYRUP contains Sorbitol

ADCO-LINCTOPENT SYRUP contains 1750 mg sorbitol in each 5 ml which is equivalent to 0,35 g/ml.

ADCO-LINCTOPENT SYRUP contains parahydroxybenzoates

ADCO-LINCTOPENT SYRUP contains parahydroxybenzoates which may cause allergic reactions (possibly delayed).

ADCO-LINCTOPENT SYRUP contains propylene glycol

ADCO-LINCTOPENT SYRUP contains 250 mg propylene glycol in each 5 ml dose which is equivalent to 50 mg per ml. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them ADCO-LINCTOPENT SYRUP, in particular if the baby is given other medicines that contain propylene glycol or alcohol. If your child than 5 years old, talk to your doctor or pharmacist before giving them ADCO-LINCTOPENT SYRUP, in particular if they use other medicines that contain propylene glycol or alcohol.

3. How to take ADCO-LINCTOPENT SYRUP

The usual doses are as follows:

Adults and children over 12 years: 10 to 20 ml three times daily.

Children 3 to 12 years: 5 to 10 ml three times daily.

Children 1 to 3 years: 2,5 to 5 ml three times daily.

Infants: 2,5 ml three times daily.

Do not exceed the recommended dose.

For oral use only. Shake the bottle before use.

If you take more ADCO-LINCTOPENT SYRUP than you should

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

If you forget to take ADCO-LINCTOPENT SYRUP

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

4. Possible Side Effects

ADCO-LINCTOPENT SYRUP can have side effects. Not all side effects reported for ADCO-LINCTOPENT SYRUP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ADCO-LINCTOPENT SYRUP, please consult your health care provider for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Chest pain (angina), tightness of the chest.
- Difficulty breathing or worsening asthma.
- Allergic reactions such as itchy skin rash (hives), swelling of the face, lips, mouth, tongue, throat, or difficulty in breathing.

These are all serious side effects. You may need urgent medical attention.

Frequent side effects may include:

- Allergic reactions, especially in hypersensitive patients.
- Potentially serious low blood potassium levels may occur.
- Muscle cramps, shakiness or twitching.
- Headache, dizziness, and nervousness.
- Gastric irritation, nausea, and vomiting.
- Skin reactions
- Increase in heart rate and/or irregular heartbeats (palpitations).

Less frequent side effects may include:

- Severe allergic reactions
- Fear, anxiety, excitement, restlessness, sleeplessness, confusion, irritability, and psychotic states.
- Weakness
- Heart rate changes
- Bronchospasm (excessive and prolonged contraction of the airway muscles causing breathing difficulty)
- Diarrhoea
- Angioedema (rapid swelling under the skin in areas such as the face, throat, arms and legs which can be life threatening if throat swelling blocks the airway), itchy rash
- Sweating

Unknown side effects may include:

- Disturbances in sugar breakdown
- An increase in liver enzymes
- Hypertension, chest pain, heart attack, low blood pressure with dizziness, fainting and flushing.
- Dyspnoea (difficulty breathing), or asthma exacerbation, feeling of tightness in chest
- Reduced Appetite, unpleasant taste, and increased saliva
- Difficulty in frequent urination and urinary retention.

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 or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) found on SAHPRAwebsite and "6.04 Adverse Drug Reaction Reporting Form," found under SAHPRA's publications: https://www.sahpra.org.za/Publications/Indenx/8. By reporting side effects, you can help provide more information on the safety of ADCO-LINCTOPENT SYRUP.

5. How to store ADCO-LINCTOPENT SYRUP

Store all medicines out of reach of children.

Store in a cool place, at or below 25 °C, in well-closed containers, protect from light.

Store in the original container.

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

Return all unused medicines 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 ADCO-LINCTOPENT contains:

Each 5 ml contains:	
Bromhexine hydrochloride	4 mg
Orciprenaline sulphate	5 mg

- The preservatives are methyl parahydroxybenzoate 0,05 % $^{m}/_{v}$ (E 218), and propyl Parahydroxybenzoate 0,01 % $^{m}/_{v}$ (E 216).

- The other ingredients are strawberry liquid flavourant, glycerine CP (glycerol) (E 422), kollidon 90/kollidon 90F (povidone), propylene glycol (E 1520), sorbitol 70% (non-crystalline) solution (E 420), purified water.

What ADCO-LINCTOPENT SYRUP looks like and contents of the pack

ADCO-LINCTOPENT SYRUP is a clear, colourless to pale yellow, strawberry flavoured syrup presented as 100 ml and 200 ml in amber glass bottles with a white, plastic, pilfer proof, screw on cap with liner. Not all pack sizes may be marketed.

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road,

Midrand

Erand Gardens,

Customer Care: 0860 ADCOCK/ 232625

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