APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

PROPRIETARY NAME STRENGTH AND PHARMACEUTICAL FORM

LINCTODYL COUGH LINCTUS (SYRUP)

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

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

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

WHAT LINCTODYL COUGH LINCTUS CONTAINS

The active substances per 5 ml is:

Dextromethorphan hydrobromide	15 mg
Ephedrine hydrochloride	7,5 mg
Ammonium chloride	125 mg
Preservative: (Hydroxybenzoate esters)	0,04 % *m/v*
Alcohol (96 %)	6 % *v/v*

Other ingredients: chloroform, citric acid monohydrate, colour supra geranine 2GS (CI 18050), flavour raspberry essence colourless, glycerol, glucose liquid, menthol, sodium citrate, saccharin sodium, purified water.

Contains sugar.

WHAT LINCTODYL COUGH LINCTUS IS USED FOR

LINCTODYL COUGH LINCTUS is a medicine for the symptomatic treatment of coughs.

BEFORE YOU TAKE LINCTODYL COUGH LINCTUS

Do not give/take LINCTODYL COUGH LINCTUS

- if you or your child are allergic (hypersensitive) to dextromethorphan hydrobromide, ephedrine hydrochloride, ammonium chloride, or any of the other ingredients of **LINCTODYL COUGH LINCTUS.**

  Some of the symptoms of an allergic reaction may include:

  - swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing.
  - skin rash.
- if you or your child have kidney or liver disease.
- if you or your child have organic heart disease.
- if you or your child are receiving digitalis (medicine for heart problems).
- In the presence of a blood clot in the heart/heart attack (coronary thrombosis).
- if you or your child have high blood pressure (hypertension).
- if you or your child have excess of thyroid hormone in the body (thyrotoxicosis).
- if you or your child are taking monoamine oxidase inhibitors (medicine used for depression) or within 10 days of stopping such treatment.

Take special care with LINCTODYL COUGH LINCTUS:

LINCTODYL COUGH LINCTUS may cause slight drowsiness in some susceptible patients (see "**Driving and using machinery")**.

Do not use continuously for more than 10 (ten) days without consulting your doctor.

Driving and using machinery:

The use of **LINCTODYL COUGH LINCTUS** leads to drowsiness which is aggravated by the simultaneous intake of alcohol and other tranquilisers. Patients should be warned against performing potentially hazardous tasks and driving, where impaired mental alertness may lead to accidents.

Taking other medicines with LINCTODYL COUGH LINCTUS:

Always tell your healthcare professional if you are taking any other medicine (This includes complementary or traditional medicines).

Please tell your doctor if you take any of the following medicine:

- monoamine oxidase inhibitors (medicine used for depression) – (see " **Do not give/take LINCTODYL COUGH LINCTUS")**

HOW TO TAKE LINCTODYL COUGH LINCTUS

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

Always take **LINCTODYL COUGH LINCTUS** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

DO NOT EXCEED THE RECOMMENDED DOSE.

The usual dosage of **LINCTODYL COUGH LINCTUS** *is:*

Adults:

2 medicine measures (10 ml) three or four times a day.

Children:

1 medicine measure (5 ml) three or four times a day.

Infants:

½ medicine measure (2,5 ml) three or four times a day.

Consult your doctor if no relief is obtained with the recommended dosage.

When to give **LINCTODYL COUGH LINCTUS**

- Leave at least 6 - 8 hours between doses.
- DO NOT GIVE MORE THAN 3-4 DOSES IN 24 HOURS.
- Use only when simple measures have failed to provide adequate relief.

How long to give **LINCTODYL COUGH LINCTUS**

Do not use continuously for more than 10 (ten) days without consulting your doctor (see "T**ake special care with LINCTODYL COUGH LINCTUS"**).

If you take more LINCTODYL COUGH LINCTUS than you should:

If you take more **LINCTODYL COUGH LINCTUS** than you should consult your doctor or pharmacist. If neither is available seek help at the nearest hospital or poison control centre.

If you forget to take LINCTODYL COUGH LINCTUS

Take the missed dose as soon as you remember it. However, if it is almost time for your next regular dose, do not take your missed dose. If you miss two or more doses, consult your doctor or pharmacist. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS:

LINCTODYL COUGH LINCTUS can have side effects.

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

- swelling face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- allergic reactions, including skin rashes (fever and lesions).

These are all serious side effects. If you have them you may have had a serious allergic reaction to **LINCTODYL COUGH LINCTUS.** You may need urgent medical attention or hospitalisation.

The side effects with **LINCTODYL COUGH LINCTUS** include:

- fear, anxiety, restlessness, irritability,
- tremor,
- insomnia,
- confusion,
- weakness,
- psychotic states,
- appetite may be reduced,
- nausea and vomiting.

Cardio-vascular system side effects are complex:

- vasoconstriction,
- the rise in blood pressure may produce brain bleeding (cerebral haemorrhage) and excess fluid in the lungs (pulmonary oedema),
- reflex slow heartbeat (bradycardia) or fast heartbeat (tachycardia) and heart arrhythmias,
- anginal pain,
- palpitations,
- cardiac arrest,
- low blood pressure (hypotension) with dizziness and flushing.

Other effects include:

- difficulty in urinating (micturition),
- inability to empty the bladder completely (urinary retention),
- shortness of breath (dyspnoea),
- altered metabolism,

- disturbances of glucose metabolism,
- sweating,
- excessive production of saliva (hypersalivation),
- headache.

Large doses of **LINCTODYL COUGH LINCTUS** may cause gastric irritation and headache but this also is unlikely to occur with the amounts contained in **LINCTODYL COUGH LINCTUS.**

Not all side effects reported for LINCTODYL COUGH LINCTUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LINCTODYL COUGH LINCTUS please consult your doctor, pharmacist or other healthcare professional for advice.

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

STORING AND DISPOSING OF LINCTODYL COUGH LINCTUS

Store all medicine out of reach of children.

Store at or below 25 °C. Protect from light.

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

Return all unused medicine to your pharmacist.

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

PRESENTATION OF LINCTODYL COUGH LINCTUS

Bottles of 100 ml and 200 ml.

IDENTIFICATION OF LINCTODYL COUGH LINCTUS

A red raspberry flavoured syrup.

REGISTRATION NUMBER

H/10.1/192

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Shanur Healthcare (Pty) Ltd

Loch House Unit 3

3A Eton Road

Parktown

Johannesburg, 2193

DATE OF PUBLICATION

Date of registration: 12 April 1977

Date of last approval by Council: 16 September 2005