APPROVED PACKAGE INSERT

Package insert

The under-mentioned information with regard to this medicine shall appear on the package insert. The information shall be presented in the format stipulated, provided that the Council may authorise any deviation from such information or such format (refer to Regulation 9 of the Act).

1 Scheduling status
2 Proprietary name and dosage form
3 Composition
4 Pharmacological classification
5 Pharmacological action
(Pharmacodynamic properties, Pharmacokinetic properties and Summary of clinical studies)
6 Indications
7 Contraindications
8 Warnings and Special Precautions
9 Interactions
10 Pregnancy and lactation
11 Dosage and directions for use
12 Side effects
13 Known symptoms of overdosage and particulars of its treatment
14 Identification
15 Presentation
16 Storage instructions
17 Registration number
18 Name and business address of the holder of the certificate of registration
19 Date of publication of the package insert.

Please find attached:

- English Package Insert

PACKAGE INSERT:

SCHEDULING STATUS: **S2**

PROPRIETARY NAME (AND DOSAGE FORM):

LINCTODYL COUGH LINCTUS (Syrup)

COMPOSITION:

Each 5 ml medicine measure contains:

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.

PHARMACOLOGICAL CLASSIFICATION:

A 10.1 Anti-tussives and expectorants

PHARMACOLOGICAL ACTION:

LINCTODYL COUGH LINCTUS is an antitussive and expectorant.

INDICATIONS:

LINCTODYL COUGH LINCTUS is recommended for the symptomatic treatment of coughs.

CONTRAINDICATIONS:

Because of its ephedrine content **LINCTODYL COUGH LINCTUS** is contra-indicated in the presence of coronary thrombosis, hypertension and thyrotoxicosis. It should be used with caution in patients with organic heart disease and those receiving digitalis.

Because of its ammonium chloride content **LINCTODYL COUGH LINCTUS** is contra-indicated in the presence of renal and hepatic disease. **LINCTODYL COUGH LINCTUS** (because of its ephedrine content) must not be given simultaneously with M.A.O. inhibitors.

WARNINGS AND SPECIAL PRECAUTIONS:

KEEP OUT OF REACH OF CHILDREN.

LINCTODYL COUGH LINCTUS may cause slight drowsiness in some susceptible patients. The effect is aggravated if alcohol is taken at the same time. Initial doses should be small in patients who are driving vehicles or who are in charge of machinery where loss of attention may lead to accidents.

DOSAGE AND DIRECTIONS FOR USE:

Adults: 10 ml (2 medicine measures)

Children: 5 ml (1 medicine measure)

Infants: 2,5 ml (½ medicine measure)

All three or four times a day.

SIDE EFFECTS:

Sympathomimetics (ephedrine) may produce a wide range of adverse effects most of which mimic

the results of excessive stimulation of the sympathetic nervous system. Central effects of sympathomimetic agents include fear, anxiety, restlessness, tremor, insomnia, confusion, irritability, weakness and psychotic states. Appetite may be reduced and nausea and vomiting may occur. Effects on the cardio-vascular system are complex: stimulation of alpha-adrenergic receptors produces vasoconstriction; the rise in blood pressure may produce cerebral haemorrhage and pulmonary oedema. There may also be a reflex bradycardia but stimulation of the B1 adrenergic receptors of the heart may produce tachycardia and cardiac arrhythmias, anginal pain, palpitations and cardiac arrest; hypotension with dizziness and flushing may occur. Other effects which may occur include difficulty in micturition and urinary retention, dyspnoea, altered metabolism, including disturbances of glucose metabolism, sweating and hypersalivation. Headache is also common. Large doses of ammonium chloride may cause gastric irritation and headache but this also is unlikely to occur with the amounts contained in **LINCTODYL COUGH LINCTUS.**

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See under side-effects.

IDENTIFICATION:

A red raspberry flavoured syrup.

PRESENTATION:

Bottles of 100 ml and 200 ml.

STORAGE INSTRUCTIONS:

Store at or below 25 °C and protect from light.

KEEP OUT OF REACH OF CHILDREN.

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 OF THE PACKAGE INSERT:

Date of registration: 12 April 1977

Date of last approval by Council: 16 September 2005