PACKAGE INSERT-DECOFED SYRUP

SCHEDULING STATUS:

S2

PROPRIETARY NAME AND DOSAGE FORM:

DECOFED SYRUP

COMPOSITION:

Each 5 ml of the syrup contains:

Tripolidine hydrochloride	1,25 mg
Pseudoephedrine hydrochloride	30,00 mg
Contains ethanol (96 %)	2,00 % *v/v*
Preservative:	
Methyl hydroxybenzoate	0,18 % *m/v*
Propyl hydroxybenzoate	0,02 % *m/v*

Excipients: glucose, glycerol, honey yucatan flavour F1588 HON34800S, purified water, quinoline yellow, saccharin sodium, sodium chloride, sodium cyclamate, sorbitol solution 70%, sucrose, sunset yellow.

Contains sugar.

PHARMACOLOGICAL CLASSIFICATION:

A 5.8 Preparations for the common cold, including nasal decongestants and antihistaminics.

PHARMACOLOGICAL ACTION:

DECOFED has sympathomimetic and antihistaminic properties.

INDICATIONS:

For the relief of symptoms associated with colds and influenza such as nasal congestion.

CONTRA-INDICATIONS:

Hypersensitivity to any of the active ingredients.

Acute asthmatic episodes.

Pregnancy and lactation.

The syrup should not be given to patients being treated with monoamine oxidase inhibitors or within fourteen days of stopping such treatment.

DECOFED syrup is contra-indicated in patients with cardiovascular disease, hypertension, hyperthyroidism, hyperexcitability, phaeo-chromocytoma, closed angle glaucoma, urinary retention and prostatic hypertrophy.

WARNINGS and SPECIAL PRECAUTIONS:

This medicine may lead to drowsiness and impaired concentration, which may be aggravated by the simultaneous intake of alcohol or any other central nervous system depressant agents.

Pseudoephedrine hydrochloride should be used with caution in patients with diabetes mellitus, hypertension, organic heart disease, cardiac decompensation or angina of

effort, and in patients receiving digitalis, quinidine or tricyclic anti-depressants. **DECOFED** syrup should be used with extreme caution in premature infants. (Not indicated for use in neonates). Paradoxical nervous system stimulation may occur especially in children. Symptoms of stimulation include insomnia, nervousness, tachycardia, tremors, muscle twitching and convulsions.

Effects on ability to drive and use machines:

Patients should be warned not to drive a motor vehicle, operate dangerous machinery or climb dangerous heights, as impaired decision making could lead to accidents.

INTERACTIONS:

Triprolidine potentiates the antimuscarinic action of atropine and tricyclic anti-depressants

Pseudoephedrine hydrochloride should be used with caution in patients receiving chloroform, cyclopropane, halothane or other halogenated anaesthetics. The effects of pseudoephedrine hydrochloride are diminished by guanethidine, reserpine and methyldopa, and may be diminished or enhanced by tricyclic anti-depressants. Pseudoephedrine hydrochloride may diminish the effects of gaunethidine.

PREGNANCY AND LACTATION:

The use of **DECOFED** syrup is contra-indicated during pregnancy and breast-feeding.

DOSAGE AND DIRECTIONS FOR USE:

Adults and children over 12 years: 1 - 2 medicine measures (5 - 10 ml) to be taken three times daily

Children 6 – 12 years: 1 medicine measure (5 ml) to be taken three times daily

Children 2 – 5 years: ½ - 1 medicine measure (2,5 ml) to be taken three times daily

Note: A doctor's advice should be obtained before administering **DECOFED** syrup to children less than 2 years of age.

SIDE-EFFECTS:

Nervous system:

Tripolidine:

Triprolidine is an antihistamine and the most common side effect is sedation, which can vary from slight drowsiness, to deep sleep, and including inability to concentrate, lassitude, dizziness, muscular weakness and inco-ordination, headache, irritability, tingling, heaviness and weakness of the hands, insomnia, tremors, muscle twitching and convulsions. Large doses may precipitate fits in epileptics.

Pseudoephedrine hydrochloride:

Giddiness, headache, sweating, muscle weakness, tremors, and insomnia.

Gastrointestinal disorders:

Tripolidine:

Nausea, vomiting, diarrhea or constipation and epigastric pain, anorexia or increased appetite, dryness of the mouth.

Pseudoephedrine hydrochloride:

Nausea, vomiting, thirst, hypersalivation

Ear and labyrinth disorders:

Tripolidine:

Tinnitus, could mask the warning signs of ototoxicity.

Psychiatric disorders:

Tripolidine:

Elation or depression, nightmares, nervousness

Pseudoephedrine hydrochloride:

Anxiety, restlessness, psychotic states, confusion

Renal and urinary disorders:

Tripolidine and pseudoephedrine hydrochloride:

Difficulty in micturition

Cardiovascular disorders:

Tripolidine:

Tightness of the chest, tachycardia, hypotension,

Pseudoephedrine hydrochloride:

Tachycardia, precordial pain, palpitations

Immune system disorders:

Tripolidine:

Allergy, anaphylaxis.

Blood and lymphatic system disorders:

Tripolidine:

Blood dyscrasias including agranulocytosis, leucopenia and haemolytic anaemia.

Skin and subcutaneous disorders:

Tripolidine:

It may suppress positive skin results and should be terminated several days before the test.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See **SIDE-EFFECTS** and **WARNINGS and SPECIAL PRECAUTIONS**.

Overdose with triprolidine may be fatal, especially in infants. Symptoms of overdose with triprolidine hydrochloride in infants and children may include excitement, ataxia, hallucinations, flushed face, dilated pupils, dry mouth, convulsions and hyperpyrexia. Deepening coma, cardio respiratory collapse and death may occur within 18 hours. Geriatric patients are more prone to hypotension and CNS depressive effects. Overdosage with pseudoephedrine hydrochloride may produce paranoid psychosis, delusions, hallucinations and nightmares.

Treatment of overdosage is symptomatic and supportive. In the event of overdose, consult your doctor, or take the patient to the nearest hospital immediately. Specialised treatment is essential as soon as possible.

The latest information regarding treatment of overdose can be obtained from the nearest poison centre.

IDENTIFICATION:

A bright yellow slightly viscous liquid.

PRESENTATION:

Amber PVC bottles of 100ml.

STORAGE INSTRUCTIONS:

Store at or below 25 ^{o}C and protect from light.

Keep out of reach of children.

REGISTRATION NUMBER:

Y/5.8/137

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

Litha Pharma (Pty) Ltd.

106 16th Road

Midrand

1686

DATE OF PUBLICATION OF THE PACKAGE INSERT

Original date of registration: 18 January 1991

Revised package insert approval: 26 July 2012