1.3.1.1

SCHEDULING STATUS: **S0**

PROPRIETARY NAME: **STEARNS COUGH SYRUP - PINE TAR AND HONEY FLAVOUR**

(AND DOSAGE FORM) **(SYRUP)**

COMPOSITION:

Each 5 ml contains:

Guaiphenesin	100 mg
Preservative:	
Sodium benzoate	*0,20 % m/v*
Contains sugar: Sorbitol 70%	2,9 g

List of excipients:

sorbitol 70% solution, glycerin [glycerol], polyvinylpyrrolidone k25, povidone / polyvidone / kollidone k2 , honey purified (irradiated), sodium citrate, saccharin sodium, Pine Bark Extract, xanthan gum, propylene glycol, acid citric monohydrate, eucalyptus oil, colour caramel 136 (wb), oil of pine tar, ethanol 96 %, purified water.

STEARNS COUGH SYRUP - PINE TAR AND HONEY FLAVOUR is tartrazine free.

PHARMACOLOGICAL CLASSIFICATION:

A 10.1 Antitussives and expectorants

PHARMACOLOGICAL ACTION:

Guaiphenesin has an expectorant action and has been reported to increase the volume and decrease the viscosity of tenacious sputum.

Pharmacokinetics:

Following oral administration, guaiphenesin is absorbed from the gastrointestinal tract.

It is metabolised and then excreted in the urine.

INDICATIONS:

Alleviation of cough associated with viscid/tenacious phlegm.

CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients.

Porphyria (see **'WARNINGS AND SPECIAL PRECAUTIONS'**).

WARNINGS AND SPECIAL PRECAUTIONS:

A persistent cough may be a sign of a serious condition. If cough persists for more than one week, tends to recur or is accompanied by high fever, skin rash, sore throat or persistent headache, consult a doctor.

STEARNS should not be given to children under 2 years unless recommended by a doctor.

Porphyria: Safety has not been established.

INTERACTIONS:

Guaiphenesin interferes with urine tests for 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

PREGNANCY AND LACTATION:

Pregnancy:

The safety of this medicine in pregnancy and lactation has not been established.

Lactation:

It is not known whether guaiphenesin is distributed into breast milk. However, problems in humans have not been documented.

DOSAGE AND DIRECTIONS FOR USE:

Adults and children 12 years and over: Oral dosage is 200 mg to 400 mg (10 ml to 20 ml) every 4 hours. Do not exceed 2 400 mg (120 ml) in 24 hours.

Children 6 to under 12 years: Oral dosage is 100 mg to 200 mg (5 ml to 10 ml) every 4 hours.

Do not exceed 1 200 mg (60 ml) in 24 hours.

Children 2 to under 6 years: Oral dosage is 50 to 100 mg (2,5 ml to 5 ml) every 4 hours.

Do not exceed 600 mg (30 ml) in 24 hours, or as directed by a doctor.

SIDE EFFECTS

Gastrointestinal disorders:

Less frequent: nausea, vomiting, diarrhoea, stomach pain and gastrointestinal discomfort.

Nervous system disorders:

Less frequent: dizziness and headache

Skin and subcutaneous tissue disorders:

Less frequent: skin rash and urticaria

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Signs and symptoms of overdosage:

Very large doses can cause gastrointestinal discomfort, nausea and vomiting.

Treatment of overdose:

Treatment is symptomatic and supportive.

IDENTIFICATION:

A dark brown syrup with an odour and taste of eucalyptus, pine tar and honey.

It is free from particulate matter.

PRESENTATION:

50 ml, 100 ml and 200 ml packed in amber PVC bottles with snap-on pilfer proof closures or

50 ml, 100 ml and 200 ml packed in amber glass bottles with screw on closures.

STORAGE INSTRUCTIONS:

Store in a well-closed container, at or below 25 °C.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

38/10.1/0002

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

Adcock Ingram Limited

1 New Road, Erand Gardens Midland, 1685

Private Bag X69, Bryanston, 2021

www.adcock.co.za

DATE OF PUBLICATION OF THE PACKAGE INSERT:

31 March 2006