SCHEDULING STATUS: **S0**

PROPRIETARY NAME AND DOSAGE FORM:

STEARNS PEPPERMINT (SYRUP)

COMPOSITION:

Each 10 ml contains:

Guaiphenesin	200 mg
Preservative:	
Nipastat	0,02 % *m/v*

Contains sugars: Glycerol and Sorbitol solution 70% (Non-crystallising)

In an alcohol-free, mentholated, peppermint-flavoured base.

List of excipients: Purified water, saccharin sodium, sodium cyclamate, propylene glycol, levomenthol, xanthan gum, glycerol, caramel colourant, peppermint oil, sorbitol solution 70 % (Non-crystallising).

PHARMACOLOGICAL CLASSIFICATION:

A 10.1 Antitussives and expectorants

PHARMACOLOGICAL ACTION:

Guaiphenesin has expectorant properties.

INDICATIONS:

Alleviation of cough.

CONTRA-INDICATIONS:

Hypersensitivity to any of the ingredients. Pregnancy. Porphyria.

Do not use in children under 2 years of age.

WARNINGS AND SPECIAL PRECAUTIONS:

Guaiphenesin should not be taken for persistent cough such as that which occurs with smoking, asthma, emphysema or where cough is accompanied by excessive secretions except under the advice and supervision of a doctor.

A persistent cough may be a sign of a serious condition. Consult a doctor if cough persists after medication has been used for 7 days, tends to recur or is accompanied by high fever, skin rash or persistent headache, or sore throat is present with cough.

Contains glycerol which may have an effect on the glycaemic control of patients with diabetes mellitus.

Patient with the rare hereditary condition of sorbitol intolerance should not take STEARNS PEPPERMINT.

INTERACTIONS:

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

PREGNANCY AND LACTATION:

Safety in pregnancy and lactation has not been established (see **"CONTRAINDICATIONS").**

DOSAGE AND DIRECTIONS FOR USE:

Adults, adolescents and geriatrics:

10 ml to 20 ml (2 to 4 medicine measures) every 4 hours.

Children: 6 to 12 years: 5 ml to 10 ml (1 to 2 medicine measures) every 4 hours.

2 to 6 years: 2,5 ml to 5 ml (½ to 1 medicine measure) every 4 hours.

Not recommended for children under 2 years of age.

SIDE EFFECTS:

Gastrointestinal discomfort (including diarrhoea, nausea, vomiting and stomach pains). Dizziness, headache, skin rash and urticaria occur less frequently.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Very large doses can cause nausea and vomiting.

Treatment is symptomatic and supportive.

IDENTIFICATION:

Brown, slightly turbid, viscous syrup. Odour of peppermint and menthol.

Taste - sweet, of peppermint and menthol.

PRESENTATION:

50 ml and 100 ml packed in clear or amber PVC bottles with snap-on pilfer proof caps.

50 ml, 100 ml and 200 ml packed in amber glass bottles with EXPE screw caps.

STORAGE INSTRUCTIONS:

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

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

33/10.1/0119

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

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