SCHEDULING STATUS: **S0**

PROPRIETARY NAME (AND DOSAGE FORM):

STEARNS GUAIPHENESIN COUGH SYRUP - CHERRY FLAVOUR (SYRUP)

COMPOSITION:

Each 10 ml contains:

Guaiphenesin	200 mg
Nipastat (Preservative)	0,02 % m/v
Contains sugars:	
Glycerol	1,500 ml
Sorbitol solution 70% (Non-crystallising)	2,74 ml

In an alcohol-free, mentholated, cherry – flavoured base.

List of excipients: Purified water, saccharin sodium, sodium cyclamate, levomenthol, xanthan gum, glycerol, colour raspberry red, flavor cherry, sorbitol solution 70 % (Non-crystallising).

PHARMACOLOGICAL CLASSIFICATION:

A.10.1 Antitussives and expectorants.

PHARMACOLOGICAL ACTION:

Guaiphenesin has expectorant properties.

INDICATIONS:

Alleviation of cough.

CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients. Pregnancy. Porphyria.

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, persistent headache, or sore throat is present with cough.

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

INTERACTIONS:

Guaiphenesin interferes with urine test for 5-hydroxyindoleacetic acid (5-HIAA) and vanillymadelic 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 – 20 ml (2 to 4 medicine measure) every 4 hours.

Children:

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

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

SIDE EFFECTS:

Gastro-intestinal discomfort (including diarrhoea, nausea, vomiting and stomach pains). Dizziness, headaches, skin rash and urticarial occurs 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:

Red, clear, viscous syrup. Odour of cherry and menthol.

Taste – sweet, of cherry and menthol.

PRESENTATION:

50 ml and 100 ml packed in clear or amber PVC bottles.

50 ml and 100 ml packed in clear or amber PET bottles.

STORAGE INSTRUCTIONS:

Store at or below 25 ºC. Protect from freezing.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

33/10.1/0055

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

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