

1.3.2 PATIENT INFORMATION LEAFLET - CLEAN COPY

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

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PROPRIETARY NAME; STRENGTH AND PHARMACEUTICAL FORM OF THE MEDICINE:

STEARNS COUGH SYRUP - PINE TAR AND HONEY FLAVOUR (SYRUP)

Read this entire leaflet carefully because it contains important information.

STEARNS is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless you still need to use STEARNS carefully to get the best-results.

- **Keep this leaflet as you may need to read it again.**
- **Do not share STEARNS with any other person**
- **Ask your pharmacist if you need more information or advice.**
- **You must see a doctor if your symptoms worsen or do not improve while taking this medicine.**

1. WHAT DOES STEARNS CONTAINS:

The active ingredient in **STEARNS** is Guaiphenesin 100 mg per 5 ml.

The syrup contains the following preservative: sodium benzoate (0, 20 % m/v).

The other ingredients contained are; citric acid monohydrate, ethanol 96 %, eucalyptus oil, glycerol, oil of pine tar, polyvinylpyrrolidone K25, propylene glycol, purified honey, purified water, saccharin sodium, sodium citrate, sorbitol 70 % solution, Pine Bark Extract, xanthan gum and permitted colourants, colour caramel,

2. WHAT STEARNS IS USED FOR:

The active ingredient guaiphenesin has an expectorant [medicine which promotes coughing and expulsion of mucous (wet or productive cough)] action and has been reported to increase the volume and decrease the viscosity of tenacious phlegm (thick mucus).

STEARNS is used for the alleviation of cough associated with viscid / tenacious phlegm (thick mucus).

3. BEFORE YOU TAKE STEARN:

Do not take Stearns:

- If you are allergic to guaiphenesin or any of the other ingredients in the preparation.
- If you have porphyria (inherited disorder of blood pigment metabolism).

Take special care with STEARNS:

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, rash, sore throat or persistent headache, consult a doctor.

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

Pregnancy and breastfeeding:

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

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

If you are pregnant or breastfeeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Taking other medicines with STEARNS:

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

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **STEARNS** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

4. HOW TO TAKE STEARNS:

SHAKE WELL BEFORE USE.

Adults and children 12 years and over:

Oral dosage is 200 mg – 400 mg (10 ml – 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 – 200 mg (5 ml – 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 mg – 100 mg (2,5 ml – 5 ml) every 4 hours.

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

If you take more STEARNS than you should (an overdose):

Very large doses can cause gastrointestinal (affecting stomach and intestines) discomfort, nausea and vomiting. Treatment by your doctor or healthcare professional is symptomatic and supportive.

Do not share your medicines with other people.

5. POSSIBLE SIDE EFFECTS

STEARNS can have side effects.

Gastrointestinal disorders:

Less frequent:

Nausea, vomiting, diarrhoea, stomach pain and gastrointestinal (affecting the stomach and intestines) discomfort.

Nervous system disorders:

Less frequent:

Dizziness and headache.

Skin and subcutaneous tissue disorders:

Less frequent:

Skin rash and urticaria (allergic skin rash).

Consult a doctor if cough persists after medication has been used for 7 days or if fever, skin rash, continuing headache, or sore throat is present with cough.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF STEARNS:

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

Protect from light.

Keep all medicines out of the reach and sight of children.

Do not use the medicine after the expiry date stated on the container.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

7. PRESENTATION OF STEARNS:

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.

8. IDENTIFICATION OF STEARNS:

A dark brown syrup with an odour and taste of eucalyptus, pine tar and honey. It is free from particulate matter.

9. REGISTRATION NUMBER:

38/10.1/0002

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

ADCOCK INGRAM (Pty) LIMITED

1 New Road, Erand Gardens Midrand, 1685

11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

31 March 2006