1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S0

PROPRIETARY NAME AND DOSAGE FORM

HAMBURG TEA (decoction)

COMPOSITION

Each 550 mg of HAMBURG TEA contains 537,5 mg senna leaves which is equivalent to 13,4 mg hydroxyanthracene glycosides as sennoside B.

Excipient:

Buchu leaves

Sugar free

CATEGORY AND CLASS

A 11.5 Laxatives

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Promotes bowel movement by one or more direct actions on the intestine.

INDICATIONS

For the treatment of occasional constipation.

CONTRAINDICATIONS

- Hypersensitivity to senna.
- Intestinal obstruction or undiagnosed abdominal symptoms.

WARNINGS AND SPECIAL PRECAUTIONS

HAMBURG TEA should not be used in the presence of abdominal pain, nausea, vomiting or for a period longer than 1 week, unless directed by a doctor. If you have noticed a sudden change in bowel habits that has persisted for a period longer than 2 weeks or have rectal bleeding or failure to have a bowel movement after use of a laxative, this may be indicative of a serious condition. Discontinue use and consult a doctor. Frequent or prolonged use of HAMBURG TEA may result in dependence on laxatives and loss of normal bowel function.

Care should be taken in patients with inflammatory bowel disease.

INTERACTIONS

Not known.

HUMAN REPRODUCTION

Not known.

DOSAGE AND DIRECTIONS FOR USE

LEAVES

Adults:

Two medicine measures taken at night and in the morning in the form of a tea, prepared as

indicated below.

Children over the age of 6 years:

One medicine measure taken at night and in the morning in the form of a tea, prepared as indicated below.

PREPARATION OF LEAVES

Place the required amount of HAMBURG TEA in a teapot and pour two cups of boiling water over. Allow to stand for five minutes and then strain. The tea may be sweetened to taste. When HAMBURG TEA is brewed as directed not less than 40 % of the stated amount of hydroxyanthracene glycosides are recovered in the tea.

SIDE EFFECTS

May cause abdominal discomfort, such as colic and cramps.

Prolonged use or overdosage may result in diarrhoea, excessive loss of water and electrolytes and possible atonic non-functioning colon. Discolouration of the urine may occur and may interfere with diagnostic tests.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

See SIDE EFFECTS.

Treatment is symptomatic and supportive.

IDENTIFICATION

Pale green leaves with a slight characteristic odour.

PRESENTATION

25 g or 50 g of dried leaves is packed in low density polyethylene sachets. The sachets are packed in an outer cardboard carton together with a leaflet.

Not all pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from light and moisture.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

E/11.5/0704

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

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Date of registration: 12 June 1997

Date of the most recent amendment to the professional information as approved by the

Authority: 12 June 1997

Namibia: NS0 04/11.5/0409

ZA_HAMBDEC_9706_00