FINAL ENGLISH PACKAGE INSERT

SCHEDULING STATUS:

S0

PROPRIETARY NAME:

HAARLEMENSIS (Drops)

COMPOSITION:

Each 5 ml contains:

Balsam Sulphuris Base	1,730 ml
Arachis oil	2,015 ml
Tar	0,163 g
Turpentine Oil	1,250 ml

PHARMACOLOGICAL CLASSIFICATION:

A - 11.5 : Medicines acting on gastrointestinal tract : Laxatives

PHARMACOLOGICAL ACTION:

The precipitated sulphur in the balsam sulphuris base has a mild laxative action and the tar has an expectorant action.

INDICATIONS:

For the treatment of constipation. (Traditionally, Haarlemensis has been recommended for kidney and bladder complaints).

CONTRA-INDICATIONS:

NOT FOR USE IN CHILDREN.

Sensitivity to any of the active ingredients.

DOSAGE AND DIRECTIONS FOR USE:

15 Drops (1 ml) in milk or wine at bedtime.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Sensitivity reactions may occur. Use of the product should be discontinued.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Excessive doses may cause gastrointestinal irritation, nausea, vomiting and diarrhoea. Excitement and convulsions or stupor and respiratory failure may occur. In acute poisoning the stomach should be emptied by aspiration and lavage. A saline purgative (30 g sodium sulphate in 250 ml water) can be given unless catharsis is already present. Demulcent drinks may be given. Large volumes of fluid should be given, provided renal function is adequate.

IDENTIFICATION:

Dark brown liquid.

PRESENTATION:

PVC bottles of 20 ml and 50 ml.

STORAGE INSTRUCTIONS:

Store below 25°C.

KEEP OUT OF REACH OF CHILDREN.

APPLICATION NUMBER:

H1625 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF APPLICANT:

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