1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS:

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PROPRIETARY NAME (and dosage form):

WONDERKROONESSENS (mixture)

COMPOSITION:

Each 5 ml contains:

Aloes Cape crude	162,5 mg
Camphor	10,0 mg
Gentian	22,5 mg
Ginger	22,5 mg
Inula	17,5 mg
Potassium carbonate	22,5 mg
Rhubarb	45,0 mg
Turmeric	22,5 mg
Valerian	22,5 mg

Excipients:

Ethanol (96 %)

CONTAINS ALCOHOL: Ethanol (96 %) 41,43 % *v/v*

SUGAR FREE

PHARMACOLOGICAL CLASSIFICATION:

A 11.10 - Medicines acting on gastro-intestinal tract (special combinations).

PHARMACOLOGICAL ACTION:

Laxative and digestive.

INDICATIONS:

Wonderkroonessens is an effective preparation for the treatment of constipation, winds and indigestion.

CONTRA-INDICATIONS:

NOT FOR USE IN CHILDREN.

Habitual use, undiagnosed abdominal pains, nausea and vomiting, and during pregnancy.

WARNINGS:

This product contains a high percentage of alcohol.

DOSAGE AND DIRECTIONS FOR USE:

Half to one medicine measureful (2,5 – 5 ml) in water morning and night, when necessary.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Continual use must be avoided. Large or overdoses may produce the following side-effects: griping, nausea, vomiting, excessive cathartic effects and gastro-intestinal irritation.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See “Side-effects and Special Precautions”. Use of the preparation must be discontinued. Treatment of acute poisoning with alcohol should include hydration with intravenous fluids, control of nausea and vomiting, and correction of electrolyte imbalances, such as hypomagnesaemia. Protection of the airway is crucial and ventilation may be required in cases of respiratory depression.

IDENTIFICATION:

A dark brown bright solution.

PRESENTATION:

Clear round PVC 20 ml bottles with a roll-on closure consisting of aluminium, lined with expanded polyethylene.

STORAGE INSTRUCTIONS:

Store at or below 25˚C.

Keep bottle tightly closed.

KEEP OUT OF REACH OF CHILDREN.

APPLICATION NUMBER:

E1486 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

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DATE OF PUBLICATION OF THIS PACKAGE INSERT:

19 October 2007

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