1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINE FOR HUMAN USE

SCHEDULING STATUS:

Unscheduled

PROPRIETARY NAME:

BALSEM SULPHURIS (Drops) - DM

COMPOSITION:

Each 5 ml contains:

Turpentine Oil	1,762 ml
Balsem Sulphuris base	3,238 ml

PHARMACOLOGICAL CLASSIFICATION:

A - 11.5 : Laxatives.

PHARMACOLOGICAL ACTION:

The precipitated sulphur in the balsem sulphuris base has a mild laxative action.

INDICATIONS:

For constipation.

CONTRA-INDICATIONS:

Sensitivity to any of the active ingredients.

WARNING:

This medicine should not be used in the presence of abdominal pain, nausea, or vomiting. Frequent or prolonged use of this preparation may result in dependence on laxatives. If you have noticed a sudden change in bowel habits that has persisted for a period of greater than 2 weeks, consult a doctor before using the laxative.

DOSAGE AND DIRECTIONS FOR USE:

10 to 20 drops (0,5 - 1,0 ml) on sugar two or three times a day.

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. Severe poisoning leads to respiratory failure. The central nervous system may be depressed leading to stupor and respiratory failure, or stimulated leading to excitement and convulsions. There may be haematuria, albuminuria, coma; the urine may have an odour of violets.

In acute poisoning the stomach should be emptied by emesis or aspiration and lavage. Give a saline purgative, such as sodium sulphate 30 g in 250 ml of water, unless catharsis is already present. Demulcent drinks can be given. Large volumes of liquids may be given provided kidney function is adequate.

IDENTIFICATION:

Thick, dark, reddish-brown clear liquid.

PRESENTATION:

20 ml bottles.

STORAGE INSTRUCTIONS:

Store below 25°C.

KEEP OUT OF REACH OF CHILDREN

APPLICATION NUMBER:

H1626 (Act 101/1965).

NAME AND BUSINESS ADDRESS OF APPLICANT:

Lennon Limited

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