# FINAL APPROVED ENGLISH PACKAGE INSERT

**SCHEDULING STATUS:**

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**PROPRIETARY NAME (and dosage form):**

LEWENSESSENS-DM (mixture)

**COMPOSITION:**

| | | |
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| **Each 5 ml contains :** | Cape Aloes | 216,667 mg |
| | Plus the alcoholic extractives of: | |
| | Ginger | 14,167 mg |
| | Rhubarb | 30,000 mg |
| | Gentian | 30,000 mg |
| | Myrrh | 20,000 mg |
| | Galangal | 10,000 mg |
| | Turmeric | 15,000 mg |
| | Ethanol (100 %) | 45%v/v |

**PHARMACOLOGICAL CLASSIFICATION:**

A 11.5 - Laxatives

**PHARMACOLOGICAL ACTION:**

Laxative and calmative.

**INDICATIONS:**

Adults: Constipation

Children: Constipation

**CONTRA-INDICATIONS:**

This product should not be taken by persons with symptoms of appendicitis or severe abdominal pains, nausea and vomiting and during pregnancy.

**WARNINGS:**

**This product contains a high percentage of alcohol.**

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:**

DO NOT EXCEED THE RECOMMENDED DOSE.

Adults : One medicine measure (5 ml) taken night and morning after meals. Lewensessens-DM is bitter and strong, and therefore some people will find it necessary to take it with cold water or beef tea.

Children: 1 year: Half medicine measure (2,5 ml).

Children: 2 – 12 years: Half to one medicine measure (2,5 – 5 ml).

**SIDE-EFFECTS AND SPECIAL PRECAUTIONS:**

The prolonged use of purgatives may produce watery diarrhoea with excessive loss of water and electrolytes, particularly potassium, muscular weakness and weight loss. Changes in the intestinal musculature associated with malabsorption, and dilation of the bowel, similar to ulcerative colitis and to megacolon, may also occur. Cardiac and renal symptoms have been reported.

The irritant action of aloes on the large intestine may cause pelvic congestion. Melanosis coli and discolouration of urine has followed the use of aloes.

The use of any laxative beyond one week is not recommended except on the advice of a doctor.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

See “Side-effects and Special Precautions”.

In large doses, aloes may cause nephritis. In overdosage the central nervous system may be depressed and the patient can become stuporous

or comatose. As in all cases of overdosage, a doctor should be called immediately. The treatment is symptomatic.

**IDENTIFICATION:**

Lewensessens-DM is a dark brown free-flowing liquid with a bitter yet acceptable taste and a characteristic unique aroma.

**PRESENTATION:**

50 ml and 100 ml bottles.

**STORAGE INSTRUCTIONS:**

Store below 25°C.

Keep container tightly closed.

KEEP OUT OF REACH OF CHILDREN.

**APPLICATION NUMBER:**

E1574 (Act 101/1965)

**NAME AND BUSINESS ADDRESS OF THE APPLICANT:**

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