1.3.1.1 **PACKAGE INSERT**

SCHEDULING STATUS: S0

PROPRIETARY NAME (AND DOSAGE FORM):

LEXIKON (SUSPENSION)

COMPOSITION:

Each 10 ml contains:

Magnesium sulphate	4g
Light Magnesium carbonate	500 mg
Preservative: Chloroform	0,1562 % *v/v*
Contains ethyl alcohol	1,71 % *v/v*

Sugar free.

The other ingredients are: xanthan gum, peppermint oil, purified water.

PHARMACOLOGICAL

CLASSIFICATION:

A 11.5 Laxatives

PHARMACOLOGICAL ACTION:

Agents, which act by their osmotic properties, thus increasing the stimulation of fluid secretion, thereby promoting bowel movement.

INDICATIONS:

For the relief of occasional constipation.

CONTRAINDICATIONS:

Hypersensitivity to the ingredients. The use of LEXIKON is inadvisable in the presence of impaired renal function as it may lead to hypermagnesium, which may result in flushing of the skin, thirst, hypotension due to peripheral vasodilatation, drowsiness, confusion, loss of tendon reflexes, respiratory depression, cardiac arrhythmias, coma and cardiac arrest. Should not be used in children with intestinal parasitic diseases.

WARNING AND SPECIAL PRECAUTIONS:

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 and loss of normal bowel function.

This medicine must not be used for a period longer than one 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, consult a doctor before using the laxative.

Should be used with caution in patients receiving digitalis glycosides.

Rectal bleeding or failure to have a bowel movement after use of a laxative may indicate a serious condition. Discontinue use and consult a doctor.

Should be given with care to those with impaired renal function.

DOSAGE AND DIRECTIONS FOR USE:

Shake the bottle before use.

This product generally produces bowel movement in half an hour to six hours.

Adults and children 12 years of age and over:

* One to four teaspoons as a single daily dose or individual doses.

Children 6 to 12 years of age:

* Oral dosage is one to three teaspoons as a single daily dose or in divided doses.

Not recommended for use in children under two years of age.

SIDE-EFFECTS:

Magnesium salts may interfere with the absorption of other substances.

Acute ingestion may cause gastro-intestinal irritation and watery diarrhoea.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See "Side-Effects."

Treatment is symptomatic and supportive.

IDENTIFICATION:

A white mixture with a peppermint odour.

PRESENTATION:

2.5L mixture in an amber HOPE polycan.

100 ml mixture in an amber plastic (PVC) bottle or white HDPE bottle.

STORAGE INSTRUCTIONS:

Store in a cool place at or below 25 °C, and out of direct sunlight.

KEEP OUT OF REACH OF CHILDREN.

APPLICATION NUMBER:

E1407 (Act 101of 1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

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DATE OF PUBLICATION OF THIS PACKAGE INSERT:

17 January 2001