APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS

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PROPRIETARY NAME AND DOSAGE FORM

FAMS MIST ALBA MIXTURE

COMPOSITION

Each 10 ml contains:

Magnesium sulphate heptahydrate	4,0 g
Light magnesium carbonate	0,50 g
Preservatives:	
Methyl hydroxybenzoate	0,1 % (m/v)
Propyl hydroxybenzoate	0,02 % (m/v)

FAMS MIST ALBA also contains the following inactive ingredients:

Peppermint oil, chloroform spirits, xanthan gum and purified water.

PHARMACOLOGICAL CLASSIFICATION

A. 11.5. Laxatives

PHARMACOLOGICAL ACTION

FAMS MIST ALBA is a saline laxative. The ingredients act by their osmotic-properties, thus increasing stimulation of fluid secretion, thereby promoting bowel movement.

INDICATIONS

For the relief of occasional constipation.

CONTRAINDICATIONS

Sensitivity to any of the ingredients.

Should not be used in patients with impaired renal function as it may lead to hypermagnesaemia which may result in flushing of the skin, thirst, hypotension due to peripheral vasodilation, drowsiness, confusion, loss of tendon reflexes, respiratory depression, cardiac arrhythrnias, coma and cardiac arrest.

WARNINGS and SPECIAL PRECAUTIONS

1. This medicine should not be used in the presence of abdominal pain, nausea or vomiting.
2. FAMS MIST ALBA should not be used for a period longer than one week, unless directed by a doctor.
3. 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.
4. 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.
5. Frequent or prolonged use of this preparation may result in dependence on laxatives and loss of normal bowel function. ‘
6. Should be used with caution in patients receiving digitalis glycosides.
7. Mucosal irritation end absorption of magnesium may occur if there is gastro intestinal atony or obstruction.

8. Magnesium salts should be administered with caution to patients with impaired renal function or those receiving digitalis glycosides. in patients with impaired renal function there may be sufficient accumulation to produce toxic effects.

INTERACTIONS

Magnesium sails may interfere with the absorption of other medicines when these are taken concomitantly. Magnesium salts bind with phosphate thus impairing its absorption from the gastro-intestinal tract.

DOSAGE AND DIRECTIONS FOR USE

This product generally produces bowel movement in half an hour to 6 hours.

Adults: 10 ml to 20 ml (two to four medicine measures) to be taken well diluted with water, preferably on an empty stomach.

The total daily dose should not exceed 20 ml.

NOT RECOMMENDED FOR CHILDREN.

SHAKE THE BOTTLE BEFORE USE

SIDE EFFECTS

The release of carbon dioxide in the stomach (from magnesium carbonate) may lead to discomfort. Acute ingestion may lead to gastro intestinal irritation and watery diarrhoea

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

After excessive administration or if renal function is impaired, hypermagnesaemia may result. Symptoms of hypermagnesaemia are flushing of the skin, thirst, hypotension, loss of reflexes,

drowsiness, confusion, muscle weakness, respiratory depression, cardiacarrhythmias, coma and cardiac arrest.

Overdosage may also lead to excessive purgation, enteritis and dehydration. If any of these symptoms appear, stop medication and consult a doctor or take the patient to thenearest hospital immediately.

Treatment of overdosage is symptomatic and supportive.

IDENTIFICATION

A white suspension with a peppermint odour. A white sediment of ±2 cm forms on standing and a thin, clear supenatant liquid with an oily appearance can be seen on top.

PRESENTATION

100 ml amber PVC bottles.

2,5 l amber HDPE containers

STORAGE INSTRUCTIONS

Store at or below 25 °C in well-closed container. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER

E752 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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DATE OF PUBLICATION OF THE PACKAGE INSERT

26 July 1996

Date of the most recently revised package insert as approved by Council:

30 September 2019