SCHEDULING STATUS Schedule 0

PROPRIETARY NAME (& DOSAGE FORM)

WILL'S MILK OF MAGNESIA

Oral suspension

COMPOSITION Each 5 ml contains:

Magnesium Oxide equivalent to Magnesium Hydroxide 425 mg

Preservatives: Sodium Benzoate 0,1% $^{m}/_{v}$

Methyl Hydroxybenzoate 0,1% $^{m}/_{v}$

Propyl Hydroxybenzoate 0,01% $^{m}/_{v}$

PHARMACOLOGICAL CLASSIFICATION

A 11.4.1 Antacids - Acid neutralisers.

PHARMACOLOGICAL ACTION

Magnesium Hydroxide has acid neutralizing properties, and diminishes the activity of pepsin in gastric secretions.

INDICATIONS

Will's Milk of Magnesia is indicated as an antacid for the relief of acid indigestion, heartburn, hyperacidity, dyspepsia, gastritis, oesophageal reflux with heartburn, and peptic ulceration.

CONTRA-INDICATIONS

Contra-indicated in patients hypersensitive to any of the ingredients. Contra-indicated 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 vasodilatation, drowsiness, confusion, loss of tendon reflexes, respiratory depression, cardiac arrhythmias, coma and cardiac arrest. Contra-indicated in patients with gastrointestinal stomas because the absorption of magnesium may occur.

WARNINGS

Do not use this product if you have kidney disease, except under the advice and supervision of a doctor. Do not take more than the maximum recommended daily dosage in a 24 hour period. Do not use the maximum dosage for more than 2 weeks, except under the advice and supervision of a doctor.

DOSAGE AND DIRECTIONS FOR USE

Antacid:

Adults 5 to 10 ml 3 to 4 times a day

Children:

6 to 12 years 2,5 to 5ml 3 to 4 times a day

2 to 6 years 2,5ml 3 to 4 times a day

This product should not be given to infants who weigh less than 2,5kg.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

Acute ingestion of Magnesium Hydroxide may lead to gastrointestinal irritation and watery diarrhoea; if renal function is impaired, hypermagnesaemia may result. Magnesium Hydroxide may interfere with the absorption of other medicines given concomitantly (e.g. tetracyclines and oral iron preparations).

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT See Side-Effects and Special Precautions. Treatment is symptomatic and supportive.

IDENTIFICATION A white suspension with an aromatic odour, which slowly separates on standing, forming a clear supernatant liquid; it is easily resuspendable with mild shaking.

PRESENTATION In 50 ml, 100 ml and 2,5 l amber plastic bottles.

STORAGE INSTRUCTIONS Store at or below 25°C but do not refrigerate. Keep well closed.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER 34/11.4.1/0238

NAME AND BUSINESS ADDRESS OF THE APPLICANT

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