SCHEDULING STATUS:

S0

PROPRIETARY NAME [and dosage form]:

BALSEM VITA WIT (Mixture)

COMPOSITION:

Each 5 ml contains:

Cassia oil	0,020 ml
Spike lavender oil	0,1164 ml
Clove oil	0,020 ml
Nutmeg oil	0,020 ml
Thyme oil	0,006 ml
Ethanol (100%)	86,70% v/v

PHARMACOLOGICAL CLASSIFICATION:

A - 11.2 : Gastro-intestinal antispasmodics and cholinolytics (anti-cholinergics)

PHARMACOLOGICAL ACTION:

The volatile principles in this preparation have a carminative action and are believed to exert some antispasmodic action on the gastro-intestinal tract.

INDICATIONS:

Gastric discomfort, flatulent colic and to counteract the griping action of purgatives.

CONTRA-INDICATIONS:

None.

WARNINGS:

This product contains a high percentage of alcohol.

DOSAGE AND DIRECTIONS FOR USE:

Adults:

1,5 - 2 ml (20 - 30 drops) in water four to five times daily, preferably after meals.

Children:

0,5 ml (10 drops) in sweetened water four to five times daily, preferably after meals.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Hypersensitivity reactions may occur.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Excessive doses of essential oils are irritant to the gastro-intestinal tract and may cause nausea, vomiting and diarrhoea. The central nervous system may be depressed leading to stupor and respiratory failure, or stimulated leading to excitement and convulsions, death has occurred with some essential oils.

There has been a report of severe toxicity following ingestion of clove oil in a child. Adverse effects included coma, acidosis, a generalised seizure, disordered blood clotting and acute liver damage.

Treatment is symptomatic and supportive.

IDENTIFICATION:

A pale yellow, clear bright solution.

PRESENTATION:

Clear glass bottles of 20 ml.

STORAGE INSTRUCTIONS:

Store below 25°C in airtight containers and protect from light.

KEEP WELL CLOSED

KEEP OUT OF REACH OF CHILDREN.

APPLICATION NUMBER:

E1517 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF APPLICANT:

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