SCHEDULING STATUS:

S0

PROPRIETARY NAME (AND DOSAGE FORM):

PEPERMENTDRUPPELS (drops)

COMPOSITION:

Each 5 ml contains :	Peppermint oil	0,5 ml
	Ethanol (100%)	81% v/v

PHARMACOLOGICAL CLASSIFICATION:

A 11.2 - Gastrointestinal antispasmodics and cholinolytics (anticholinergics).

PHARMACOLOGICAL ACTION:

Pepermentdruppels exerts a carminative action.

INDICATIONS:

Pepermentdruppels aids in the relief of flatulence.

CONTRA-INDICATIONS:

Not to be taken by children younger than 12 years of age.

Persons who are hypersensitive to the active ingredient.

WARNINGS:

This product contains a high percentage of alcohol.

DOSAGE AND DIRECTIONS FOR USE:

Take 2 ml three times daily in water, half to one hour before food, increased to 4 ml three times daily if necessary.

Not to be taken by children younger than 12 years of age.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Peppermint oil can be irritant.

Pepermentdruppels may cause allergic reactions in hypersensitive patients.

Reported reactions include erythematous skin rash, headache, bradycardia, muscle tremor, and ataxia. Heartburn has also been reported.

If symptoms persist, seek medical advice.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See “Side-effects and Special Precautions”. Treatment of acute poisoning with alcohol should include hydration with intravenous fluids, control of nausea and vomiting, and correction of electrolyte imbalances, such as hypomagnesaemia. Protection of the airway is crucial and ventilation may be required in cases of respiratory depression.

Treat with symptomatic and supportive therapy.

IDENTIFICATION:

A colourless, clear liquid with a strong odour of peppermint.

PRESENTATION:

Glass and PVC vials of 20 ml.

STORAGE INSTRUCTIONS:

KEEP WELL CLOSED

KEEP OUT OF REACH OF CHILDREN.

Store below 25ºC in airtight containers and protect from light.

APPLICATION NUMBER:

E1950 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

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