FINAL APPROVED PACKAGE INSERT

SCHEDULING STATUS:

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PROPRIETARY NAME:

BORSDRUPPELS

COMPOSITION:

Each 5 ml contains:

Liquorice extract	1,125 g
Fennel Oil	0,003 ml
Aniseed Oil	0,009 ml
Ethanol (100%):	13,50% v/v

PHARMACOLOGICAL CLASSIFICATION:

A - 10.1 : Antitussives and expectorants

PHARMACOLOGICAL ACTION:

BORSDRUPPELS has demulcent and expectorant properties. Its demulcent action protects the surfaces of the pharynx from irritation and so reduces the frequency of coughing. Its expectorant action produces an increase in the secretions of the respiratory tract and so reduces the viscosity of the mucous,

thereby inducing a productive cough which is less painful to the patient.

INDICATIONS:

BORSDRUPPELS provides a symptomatic relief from cough, croup and bronchitis.

CONTRA-INDICATIONS:

BORSDRUPPELS should not be administered to patients suffering from hypertension.

WARNINGS:

This product contains a high percentage of alcohol.

DOSAGE AND DIRECTIONS FOR USE:

Adults: One to two (5 ml) medicine measures.

Children: 1,0 - 1,5 ml (15 - 20 drops).

Three times a day, in water, tea or honey.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

BORSDRUPPELS in large doses may cause sodium retention and potassium loss leading to hypertension, water retention, and electrolyte imbalance.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See “Side-effects and Special Precautions”. The use of this medicine should be discontinued.

IDENTIFICATION:

Dark brown, cloudy liquid with the odour of anise.

PRESENTATION:

Bottles of 20 ml.

STORAGE INSTRUCTIONS:

Store below 25°C, and keep container tightly closed.

KEEP OUT OF REACH OF CHILDREN.

APPLICATION NUMBER:

G543 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF APPLICANT:

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DATE OF PUBLICATION OF THIS PACKAGE INSERT:

04 April 1985