FINAL APPROVED ENGLISH PACKAGE INSERT

SCHEDULING STATUS:

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PROPRIETARY NAME (and dosage form):

BALSEM-KOPIVA (Drops)

COMPOSITION:

Balsam Copaiba B.P.C. 1949.

PHARMACOLOGICAL CLASSIFICATION:

A - 18.5 : Urinary tract antiseptics.

PHARMACOLOGICAL ACTION:

Balsem-Kopiva is carminative and is said to possess mild urinary antiseptic properties.

INDICATIONS:

Balsem-Kopiva is traditionally used as a household remedy for the treatment of mild kidney ailments, backache and inflammation of the bladder.

CONTRA-INDICATIONS:

NOT FOR USE IN CHILDREN.

Sensitivity to the product.

DOSAGE AND DIRECTIONS FOR USE:

10 to 30 drops (0,5 - 2,0 ml) on sugar, or in milk three times a day.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

In some patients it may produce a morbilliform rash and its continued use tends to cause digestive disturbances.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See “SIDE-EFFECTS AND SPECIAL PRECAUTIONS”. Use thereof must be discontinued.

IDENTIFICATION:

Viscous yellow to golden brown transparent liquid with a characteristic odour.

PRESENTATION:

Bottles of 20 ml.

STORAGE INSTRUCTIONS:

Store below 25 °C.

KEEP OUT OF THE REACH OF CHILDREN.

APPLICATION NUMBER:

H1632 (Act 101/1965).

NAME AND BUSINESS ADDRESS OF APPLICANT:

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