

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Happinose 0.3% Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Levomenthol 0.3% w/w.

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Ointment

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

By topical administration to the nasal passages for the symptomatic relief of nasal congestion associated with the common cold, catarrh, head colds and hay fever. If desired, Happinose may also be rubbed onto the lips, nose, throat and chest and between the shoulders.

4.2 Posology and method of administration

Adults and elderly

Blow the nose before application. Carefully apply half an inch of Happinose inside each nostril using the little finger and inhale.

If desired, Happinose can also be rubbed on the bridge of the nose, throat and chest and between the shoulders.

Re-apply four hourly as required. if symptoms persist after 10-14 days, consult your doctor.

Children over 10 years

As above, but one half the adult dose

Children 5-9 years

As above but one quarter the adult dose

Children under 5 years

Not recommended

4.3 Contraindications

Known sensitivity to the preparation or any of its ingredients.
Children under 5 years of age

4.4 Special warnings and special precautions for use

For external use only. Keep away from the eyes and keep out of reach of children. Hands should be washed after use.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Pregnancy and lactation

There have been no reports of abnormalities or adverse effects associated with the use of Happinose in pregnant women or nursing mothers.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

None stated.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

There is no specific antidote to Happinose. Symptomatic methods should be instituted.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

When inhaled, menthol produces a sensation of cooling in the nasal passages thus providing symptomatic relief.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cineole (Eucalyptol)
Geranium Oil
White Soft Paraffin
Light Liquid Paraffin

6.2 Incompatibilities

None stated.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 25°C. Keep the container tightly closed.

6.5 Nature and contents of container

Membrane sealed internally lacquered aluminium tube with HDPE screw cap.

Pack size 14g.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Diomed Developments Ltd.

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8. MARKETING AUTHORISATION NUMBER

PL 00173/ 0177

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19/04/2005

10 DATE OF REVISION OF THE TEXT

21/05/2015