

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Snufflebabe Vapour Rub

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Eucalyptus Oil 2.00 %, Menthol 1.50 %, Thyme Oil 0.50%.

For excipients, see 6.1

### **3 PHARMACEUTICAL FORM**

Inhalation vapour ointment

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

To give relief from congestion of the upper respiratory tract.

#### **4.2 Posology and method of administration**

Topical.

Snufflebabe may be used without professional supervision from the age of three months. Below this age it is recommended that the mother consults her GP, Pharmacist or Health Visitor.

Rub a small amount on the upper chest and throat. Alternatively Snufflebabe may be placed in a tissue or handkerchief in the clothing. To eliminate the

possibility of very young children transferring the product to their eyes, on their fingers, the handkerchief may be tied to their cot just out of reach.

Body heat causes the aromatic oils to vaporise from the product so that they may be breathed in and help give relief of the upper respiratory tract (blocked nose).

### **4.3 Contraindications**

Keep out of reach of children.

### **4.4 Special warnings and precautions for use**

It is dangerous to apply an ointment containing menthol to the nostrils of infants. If symptoms persist consult your GP.

Do not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

### **4.5 Interaction with other medicinal products and other forms of interaction**

No significant interactions have been reported.

### **4.6 Fertility, pregnancy and lactation**

None stated.

### **4.7 Effects on ability to drive and use machines**

Not applicable, none reported.

## **4.8 Undesirable effects**

Could give rise to hypersensitivity reactions including contact dermatitis. If symptoms persist consult you GP.

### 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, website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

## **4.9 Overdose**

Overdosage may result in skin irritation.

Misuse/Accidental ingestion:

Swallowing of the ointment might cause gastrointestinal symptoms like vomiting and diarrhoea. Treatment is symptomatic.

Following oral ingestion, symptoms of overdosage may include colic, dizziness, delirium, muscle twitching, epileptiform convulsions and depression of the central nervous system. Breathing may be difficult. There may also be haematuria and albuminuria.

Patients with severe gastrointestinal or neurological symptoms of poisoning should be observed and treated symptomatically. Do not induce vomiting.

Convulsions may be controlled by the intravenous administration of diazepam 5-10 mg.

# **5 PHARMACOLOGICAL PROPERTIES**

## **5.1 Pharmacodynamic properties**

Menthol, Eucalyptus Oil and Thyme Oil have all been used for many years for inhalation and in vapour rubs where they have given relief from congestion of the upper respiratory tract.

## **5.2 Pharmacokinetic properties**

Not applicable.

## **5.3 Preclinical safety data**

Not applicable.

# **6 PHARMACEUTICAL PARTICULARS**

## **6.1 List of excipients**

White Soft Paraffin

## **6.2 Incompatibilities**

None known.

## **6.3 Shelf life**

36 months.

## **6.4 Special precautions for storage**

Do not store above 25°C and do not freeze.

## **6.5 Nature and contents of container**

Polyethylene Terephthalate jar with screw on polypropylene cap: 35 g.

## **6.6 Special precautions for disposal**

Snufflebabe may be used without professional supervision from the age of three months. Below this age it is recommended that the mother consults her GP, Pharmacist or Health Visitor.

## **7 MARKETING AUTHORISATION HOLDER**

Dendron Brands Limited  
94, Rickmansworth Road  
Watford  
Hertfordshire  
WD18 7JJ  
United Kingdom

## **8 MARKETING AUTHORISATION NUMBER(S)**

PL 52731/0009

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

28<sup>th</sup> September 2004

## **10 DATE OF REVISION OF THE TEXT**

02/02/2021