

## LEOPARD VAPOUR RUB

### SUMMARY OF PRODUCT CHARACTERISTICS

#### 1. NAME OF THE MEDICINAL PRODUCT

**LEOPARD VAPOUR RUB**

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

**Batch Size: 500 kg**

Name of constituent	Label claim	Quantity used per 25 gm	Reason For Inclusion
Menthol BP*	2.82% w/w	0.7755 g	Active
Camphor BP*	5.25 % w/w	1.444 gm	Active
Thymol BP*	0.10 % w/w	0.0275 gm	Active
Turpentine Oil BP*	5.57 % v/w	1.3205 gm	Active
Eucalyptus Oil BP*	1.49 % v/w	0.376 gm	Active
Nutmeg Oil IH	0.54 % v/w	0.133 gm	Active
Paraffin Wax Hard BP	-	1.25 gm	Ointment Base
White Soft Paraffin** IH (Vaporolatum Grade)	-	19.9223 gm	Ointment Base

\* 10 % Overages added.

\*\* 1% extra quantity added to compensate handling losses

Definitions: BP: British Pharmacopoeia

IH: In House Specification

#### 3. PHARMACEUTICAL FORM

Topical Ointment

#### 4. CLINICAL PARTICULARS

##### 4.1 Therapeutic indications

LEOPARD Vapour rub is indicated for the symptomatic relief of nasal catarrh and congestion, sore throat, also cough due to colds.

##### 4.2 Posology and method of administration

Dosage: Adults: Rub LEOPARD Vapour rub liberally on the chest, throat and back. Rub in well over the whole area and leave nightclothes loose for easy inhalation. or

Melt two teaspoons of LEOPARD Vapour rub in very hot water and inhale the vapours.

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Children (over 2 years):

Administration: Apply lightly to chest and back. Rub gently and leave clothes loose for easy inhalation.

### 4.3 Contraindications

Should not be swallowed or placed near mouth or nostrils.

### 4.4 Special warnings and precautions for use

Do not swallow or place in nostrils.

Keep out of the reach of children. If symptoms persist consult your doctor.

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

Not Applicable

### 4.6 Pregnancy and lactation

Although there is no evidence of any risk when Leopard Vapour rub is used in pregnancy, such use is not recommended without medical advice.

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

None.

### 4.8 Undesirable effects

Use of large amounts of Leopard can lead to irritant or allergic contact dermatitis.

### 4.9 Overdose

It is unlikely that a sufficient volume of the Leopard Vapour Rub could be ingested to cause any medical problems. In the event of accidental eye contact, wash with Lukewarm water.

## 5. PHARMACOLOGICAL PROPERTIES

The menthol and eucalyptus oil in the formulation interact with a receptor located within sensory neurons in the nose which are also responsible for the detection of cold temperatures. This interaction causes the sensation of nasal cooling, feeling similar to breathing cold air through the nose.

### 5.1 Pharmacodynamic properties

Camphor, eucalyptus oil, menthol, thymol, turpentine oil is a topical combination of cough suppressants and analgesics indicated for the temporary relief of minor aches and pains of muscles and joints and cough due to the common cold.

### 5.2 Pharmacokinetic properties

Camphor; eucalyptus oil; menthol is a topical combination of cough suppressants and analgesics indicated for the temporary relief of minor aches and pains of muscles and joints and cough due to the common cold. Camphor is a cyclic ketone for the hydroaromatic terpene group that has been used for medicinal purposes, including its antitussive and analgesic properties, for centuries. It was originally obtained by distillation of bark chips from the camphor tree, *Cinnamomum Camphora* but is now produced synthetically. Many species of the genus *Eucalyptus* from the *Myrtaceae* family are used in

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medicine for a variety of medical conditions; the monoterpenoid components of the aromatic constituents of the essential oils from Eucalyptus are commercially available for the treatment of the common cold and other symptoms of respiratory infections. Local effects including mild analgesia, cooling sensation, irritant/counter-irritant effect, and vasodilation have been attributed to topical menthol application.

### 5.3 Preclinical safety data

No additional data of relevance.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Paraffin Wax Hard BP, White soft paraffin IH (Vaporolatum Grade)

### 6.2 Incompatibilities

None.

### 6.3 Shelf life

24 months.

### 6.4 Special precautions for storage

Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

### 6.5 Nature and contents of container

Leopard vapour Rub is packed in 25 gm blue plastic (PP) container with green coloured plastic cap.

### 6.6 Special precautions for disposal and other handling

None

## 7. MARKETING AUTHORISATION HOLDER

SHALINA HEALTHCARE Nigeria Limited

## 8. Finished Product Manufacturer

SHALINA LABORATORIES PVT. LTD.

Manufacturing Site Address:

**Gopaldas Visram & Co. Ltd**, Plot No – A – 590/591, MIDC, TTC Industrial Area, Mahape,  
Navi Mumbai – 400 710, Maharashtra, India

## 9. Date of Revision of Text

Every two years

## 10. Legal category

Over The Counter product