

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Tiger Balm Red Ointment

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

D-Camphor 11.0 % w/w

Menthol 10.0 % w/w

Cajuput Oil 7.0 % w/w

Clove Oil 5.0 % w/w

For a full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Ointment.

Soft, reddish-brown ointment with odour of menthol and camphor.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

For the symptomatic relief of minor muscular aches and pains.

Tiger balm red is indicated in adults and children aged 2 years and older.

### 4.2 Posology and method of administration

#### Posology

Adultsandchildrenaged 2 years and older:

To be rubbed gently on the affected parts of skin as necessary (usually 2 to 3 times daily).

### 4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1. Do not use on children under 2 years of age.

### 4.4 Special warnings and precautions for use

For external use only. Wash hands immediately after use. Do not apply to wounds, damaged or irritated skin, discontinue use if irritation develops. Avoid contact with the eyes, mucous membranes or other tender areas. Do not bandage tightly. Keep out of reach of children. If symptoms persist after two weeks, a doctor should be consulted.

Healthcare professionals should be aware that if this product comes into contact with dressings, clothing or bedding, the fabric can be easily ignited with a naked flame. Patients should be warned of this risk and advised to keep away from fire when using this product.

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

Not applicable.

### 4.6 Fertility, pregnancy and lactation

Avoid excessive use during pregnancy and lactation.

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

Not applicable.

**4.8 Undesirable effects**

Adverse reactions reported from extensive post-marketing experience are tabulated below by System Organ Class and frequency.

The following convention has been utilised for the classification of undesirable effects: Very common ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $< 1/10$ ), uncommon ( $\geq 1/1,000$  to  $< 1/100$ ), rare ( $\geq 1/10,000$  to  $< 1/1,000$ ), very rare ( $< 1/10,000$ ), not known (cannot be estimated from available data).

System Organ Class	Adverse Drug Reaction	Frequency
General disorders and administration site conditions	Burn at application site	Not known

May give rise to hypersensitivity reactions, including contact dermatitis.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

**4.9 Overdose**

Over dosage may result in skin irritation.

Misuse:

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

Acute poisoning was observed after significant accidental consumption, with nausea, vomiting, abdominal pain, and headache, vertigo, feeling hot/flushing, convulsions, respiratory depression and coma.

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

**5 PHARMACOLOGICAL PROPERTIES****5.1 Pharmacodynamic properties**

Menthol and camphor have mild analgesic and rubefacient properties.

Cajuput oil is a mild counter irritant.

Clove oil is rubefacient and slightly analgesic with preservative properties.

**5.2 Pharmacokinetic properties**

When used as directed, absorption is expected to be insignificant.

### **5.3 Preclinical safety data**

None stated.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Partly Dementholised mint oil  
Cinnamon oil  
Yellow soft paraffin  
Hard paraffin

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

Four years.

### **6.4 Special precautions for storage**

Do not store above 25°C.

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

Glass screw top jar containing 19g or 30g of Tiger Balm Red, or a slip lid tin containing 4 or 8g of Tiger Balm Red.  
Not all pack sizes may be marketed.

### **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Chefaro Ireland DAC  
The Sharp Building  
Hogan Place  
Dublin 2  
Ireland

## **8 MARKETING AUTHORISATION NUMBER**

PA1186/014/001

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

Date of first authorisation: 15 October 1991

Date of last renewal: 15 October 2006

**10 DATE OF REVISION OF THE TEXT**

February 2022