

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Tiger Balm White Ointment

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Camphor 11.0% w/w  
Levomenthol. 8.0% w/w  
Cajuput Oil 13.0% w/w  
Clove Oil 1.5% w/w

For a full list of excipients see section 6.1

## 3 PHARMACEUTICAL FORM

Ointment.

A whitish ointment with a characteristic odour of camphor and menthol.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

#### **Adults and children over 2 years:**

For the symptomatic relief of minor muscular aches and pains. Do not use on children under 2 years.

#### **Adults only:**

For the treatment of tension headache.

### 4.2 Posology and method of administration

#### ***Muscular aches and pains (Adults and children over 2 years):***

To be rubbed gently on the affected parts of skin as necessary (usually 2 to 3 times daily). If symptoms persist after two weeks, a doctor should be consulted (see section 4.4). Do not use on children under two years of age.

#### ***Tension headache (Adults only):***

Rub the ointment onto the forehead or temples and lightly massage in a circular motion. Use a pea-sized quantity of ointment (approximately 0.5g or less), sufficient to lightly cover the affected area.

Repeat the application at 30 minutes and one hour after the initial application, if needed. If symptoms last continuously for 24 hours or recur repeatedly within the next 7 days, medical advice should be sought (see section 4.4).

Tiger Balm White Ointment should only be applied to the forehead or the temples. Do not use in children.

### 4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1

Asthma or other diseases of the respiratory tract that involve hypersensitivity of the airways.

Skin disease, open wounds, inflamed or irritated skin.

Use in infants and children under 2 years, due to the risk of respiratory collapse.

Non tension headache. Non tension headaches include those associated with nausea, vomiting and dizziness; visual disturbance; a unilateral headache; a headache presenting on waking from sleep and/or following strenuous exercise.

### 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 apply to the nostrils or inhale. Do not bandage. Keep out of the reach and sight of children.

**Muscular aches and pains:** if symptoms persist after two weeks, a doctor should be consulted (see section 4.2).

**Headache:** if symptoms last continuously for 24 hours or recur repeatedly within the next 7 days, medical advice should be sought (see section 4.2).

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.

Substances containing menthol, camphor or cajuput oil have been reported to cause apnoea, instant collapse or laryngospasm, throat spasms or breathing difficulties in infants and young children following nasal use.

#### 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 HPRC 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. Camphor is also a counter-irritant.

Cajuput oil is a stimulant and mild rubefacient.

Clove oil is a counter-irritant and mild analgesic with preservative properties.

### **5.2 Pharmacokinetic properties**

Camphor and menthol are well absorbed when applied topically, and produce a local effect. The absorption properties of cajuput oil are not known but clove oil appears to be poorly absorbed.

### **5.3 Preclinical safety data**

None stated.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Dementholised Mint 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, or a slip lid tin containing 4 or 8g.  
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**

PA1186/014/002

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

Date of first authorisation: 26 July 1999

Date of last renewal: 26 July 2009

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

February 2022