

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Combudoron Lotion.

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients per 100 ml:

2.5 g *Arnica montana* L whole plant (tincture (1=2) in 30% w/w ethanol) and  
47.5 g *Urtica urens* L herb (tincture (1=2) in 30% w/w ethanol)

For excipients, see 6.1.

#### 3 PHARMACEUTICAL FORM

Cutaneous solution.

A clear to slightly turbid, olive green to brown mobile liquid, with a characteristic odour of nettles.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

Traditionally used for the relief of sunburn, insect bites, minor burns and minor rashes including nettle rash.

##### 4.2 Posology and method of administration

Dilute 1 teaspoonful (5 ml) in a glassful (200ml) of cooled boiled water.  
Soak a piece of lint in the solution and apply as a compress. Keep moist.  
Apply the solution undiluted to insect bites.

Children and the elderly:

The adult dose is appropriate

##### 4.3 Contraindications

Do not use in patients known to be sensitive to *Arnica montana* L

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

In the rare case of sensitivity to *Arnica montana* L local irritation and redness may occur.

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

None known

## 4.6 Pregnancy and lactation

Pregnancy: There is no evidence of the safety of the product in human pregnancy, nor is there any evidence from animal studies. Although no adverse reactions have been observed, the use of the product during pregnancy should be avoided unless under the guidance of a medical practitioner.

Lactation: there is no evidence to suggest that the product should not be used during lactation.

## 4.7 Effects on ability to drive and use machines

None known

## 4.8 Undesirable effects

None known

## 4.9 Overdose

There are no known data on overdose. There are no grounds for supposing that any adverse effects would result from single or repeated excessive topical application of this product.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

No information in this area is presently available

## 5.2 Pharmacokinetic properties

No information in this area is presently available

## 5.3 Preclinical safety data

This product has been marketed in the UK for over 50 years. This section is therefore not applicable.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Ethanol 90 %  
Purified Water

## 6.2 Incompatibilities

Not applicable

## 6.3 Shelf Life

3 years.

## 6.4 Special precautions for storage

Do not store above 25°C.

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

50 and 100 ml amber glass bottles fitted with a HDPE dropper insert and a tamper evident HDPE screw cap closure.

Not all pack sizes may be marketed.

### **6.6 Instructions for use and handling**

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Weleda (UK) Ltd,  
Heanor Road,  
Ilkeston,  
Derbyshire,  
DE7 8DR,  
United Kingdom.

## **8 MARKETING AUTHORISATION NUMBER**

PA 407/7/1

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

Date of first authorisation: 18 February 1994

Date of last renewal: 18 February 2004

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

March 2004