

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Kamillosan Soothing Ointment

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tube of Kamillosan Soothing Ointment contains 10.5% extracts of chamomile (*chamomilla nobilis* flowers) standardised to give 0.01% L- $\alpha$ -bisabolol active ingredient.

For excipients, see section 6.1.

#### 3 PHARMACEUTICAL FORM

Ointment

Light brown ointment with a characteristic odour.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

For the prophylaxis and treatment of uncomplicated inflammation of the skin including sore nipples, nappy chafe, nappy rash and chapped hands.

##### 4.2 Posology and method of administration

Kamillosan Soothing Ointment is for topical application as follows:

Sore nipples in nursing mothers: after breast feeding. The nipple area should be cleansed of ointment prior to breast feeding.

Nappy chafe and nappy rash: at change of nappy.

Other conditions: twice daily as necessary.

##### 4.3 Contraindications

None known.

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

Care should be taken when applying Kamillosan Soothing ointment in those with known sensitivity to the plants of the Compositae family.

If symptoms persist for more than 2 weeks the patient should consult their doctor.

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

Reports of interactions between chamomile and Warfarin have been noted when given orally. Such interactions have not been reported with topical chamomile.

#### **4.6 Pregnancy and lactation**

Kamillosan may be used during pregnancy and is recommended during lactation.

It is recommended that healthcare professionals have knowledge about herbal drugs during pregnancy.

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

None.

#### **4.8 Undesirable effects**

Hypersensitivity and anaphylaxis reactions have been reported. However, they are very rare events.

#### **4.9 Overdose**

There are no known symptoms of overdosage.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Kamillosan possesses topical anti-inflammatory properties due to the presence of the natural anti-inflammatory substance L - a - bisabolol.

#### **5.2 Pharmacokinetic properties**

Kamillosan would be expected to remain localised at the site of application.

#### **5.3 Preclinical safety data**

There is none applicable.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Yellow beeswax  
Emulsifying wax  
Wool fat  
Yellow soft paraffin  
Maize oil  
Mixed esters of p-hydroxybenzoic acid (preservative) - Nipasept

#### **6.2 Incompatibilities**

Not applicable.

#### **6.3 Shelf Life**

2 years.

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

Do not store above 25°C.

Keep the tube in the outer carton in order to protect from moisture.

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

Aluminium tube containing 24g, 30g, 50g, 100g & 125g ointment.

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**

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### **8 MARKETING AUTHORISATION NUMBER**

PA 899/15/1

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

Date of first authorisation: 18 February 2000

Date of last renewal: 18 February 2005

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

September 2009