

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Kamillosan Chamomile Ointment

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each tube or sachet of Kamillosan Ointment contains 10.5% extracts of chamomile standardised to give 0.01% L-  $\alpha$ -bisabolol active ingredient.

### **3 PHARMACEUTICAL FORM**

Light brown ointment with Characteristic odour.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

For 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 ointment is for topical application as follows:

Sore nipples in nursing mothers: after 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**

None known

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

None known

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

Kamillosan may be used during pregnancy and lactation.

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

None.

#### **4.8 Undesirable effects**

None known.

#### **4.9 Overdose**

There are no known symptoms of overdosage.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

The chamomile extract possesses topical anti-inflammatory properties due to the presence of the natural anti-inflammatory substance  $\alpha$ -bisabolol.

#### **5.2 Pharmacokinetic properties**

Not applicable

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

There is none applicable

### **6 PHARMACEUTICAL PARTICULARS**

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

Beeswax BP, Emulsifying wax BP, anhydrous lanolin BP, yellow soft paraffin BP, maize oil and mixed esters of p-hydroxybenzoic acid (preservative)

#### **6.2 Incompatibilities**

None known

#### **6.3 Shelf life**

2 years

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

Store in a dry place below 25°C.

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

Aluminium tubes containing 5, 20, 24, 30, 50, 100 and 125g of ointment.

Sachets containing 1 and 1.5g of ointment

**6.6 Special precautions for disposal**

None.

**7 MARKETING AUTHORISATION HOLDER**

Goldshield Pharmaceuticals Ltd.  
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**8 MARKETING AUTHORISATION NUMBER(S)**

PL 12762/0039

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

01<sup>ST</sup> October 1999

**10 DATE OF REVISION OF THE TEXT**

December 2009