# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Kamillosan Chamomile 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-α-bisabolol active ingredient.

Excipients: Contains wool fat 28% w/w, Nipasept Sodium 0.1% w/w (containing Methyl parahydroxybenzoate E218, Ethyl parahydroxybenzoate E214 and Propyl parahydroxybenzoate E216)
Contains Emulsifying wax BP (containing cetostearyl alcohol 90%w/w and 10%w/w Sodium laurilsulfate)

For a full list of 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

Previous hyper-sensitivity to active ingredients or excipients.

### 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 Fertility, 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 (containing Cetostearyl alcohol and Sodium laurilsulfate)
Wool fat
Yellow soft paraffin
Maize oil
Nipasept Sodium (containing Ethyl parahydroxybenzoate E214, Propyl parahydroxybenzoate E216 and Methyl parhydroxybenzoateE218)

## 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

Chefaro Ireland Limited
First Floor, Block A,
The Crescent Building,
Northwood Office Park,
Dublin 9

## 8 MARKETING AUTHORISATION NUMBER

PA 1186/007/001

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

Date of first authorisation: 18 February 2000

Date of last renewal: 18 February 2010

## 10 DATE OF REVISION OF THE TEXT

November 2011