



SUMMARY OF PRODUCT CHARACTERISTICS

PRODUCT SUMMARY

1. NAME OF THE MEDICINAL PRODUCT

Kamillosan 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 - α - bisabolol active ingredient.

3. PHARMACEUTICAL FORM

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 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 Special Precautions for Use

None known

4.5 Interactions with other Medicaments 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 L - α - bisabolol.

5.2 Pharmacokinetic Properties

Not applicable

5.3 Pre clinical 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 1.5 g of ointment.

6.6 Instructions for Use/Handling

None

ADMINISTRATIVE DATA

7. MARKETING AUTHORISATION HOLDER

Goldshield Pharmaceuticals Ltd
NLA Tower
12-16 Addiscombe Road
Croydon
CR0 0XT
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 12762/0039

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 1999

10. DATE OF (PARTIAL) REVISION OF TEXT

August 1996