

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Silcock's Base Cream.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Excipient: Cetostearyl alcohol (a component of the emulsifying wax).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.

White, uniform cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Silcock's Base is used as a moisturising cream and base for other medicaments.

Silcock's Base is recommended for the treatment of eczema as a moisturiser and soap substitute.

4.2 Posology and method of administration

Route of Administration: Cutaneous.

Recommended Dosage Schedule: Apply freely to the skin.

4.3 Contraindications

There are no known contra-indications to the use of Silcock's Base.

4.4 Special warnings and precautions for use

Not applicable.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable.

4.6 Pregnancy and lactation

Not applicable.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

None known.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Emulsifying wax (containing cetostearyl alcohol, sodium laurilsulfate and purified water)

White soft paraffin

Phenoxyethanol

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

Silcocks's Base is filled into 70 ml, 150 ml and 650 ml white glossy polypropylene screw cap jars which are fitted with a cap, holding 50 g, 100 g and 500 g respectively.

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

Rowa Pharmaceuticals Limited
Bantry
County Cork

8 MARKETING AUTHORISATION NUMBER

PA 0074/049/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th March 1997

Date of last renewal: 7th March 2007

10 DATE OF REVISION OF THE TEXT

May 2007