

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

LactiCare

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Pyrrolidone Carboxylate	2.5 % w/w
Lactic Acid	5.0 % w/w

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Cutaneous emulsion.
A white viscous lotion.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

LactiCare is indicated for the symptomatic relief of hyperkeratotic and other chronic dry skin conditions.

4.2 Posology and method of administration

LactiCare can be used as often as required. Apply to the affected skin and rub in gently.

4.3 Contraindications

None known.

4.4 Special warnings and special precautions for use

Keep away from the eyes and mucous membranes. Should contact with the eyes occur, remove with water.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

There are no restrictions on the use of LactiCare in pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Occasionally a transient mild stinging sensation may occur. Should prolonged irritation develop when used on abraded or inflamed skin, discontinue use.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

LactiCare contains both the humectant sodium pyrrolidone carboxylate and lactic acid formulated in an oil in water emulsion base to promote hydration

5.2 Pharmacokinetic properties

Not applicable; the product is for cutaneous use and acts locally at the site of application.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer 940
Imidurea
Dehydroacetic Acid
Sodium Hydroxide
Polyethylene Glycol Ether Complex
Self-emulsifying Glyceryl Monostearate
Cetyl Alcohol
Isopropyl Palmitate
Light Liquid Paraffin
Myristyl Lactate
Perfume, Antaria Essence 73/82
Purified Water

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

Three years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

High density polyethylene bottles or a HDPE tube fitted with flip-top cap, containing 150 ml.

6.6 Instructions for use and handling

None

7 MARKETING AUTHORISATION HOLDER

Stiefel Laboratories (UK) Ltd.,
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8 MARKETING AUTHORISATION NUMBER

PA 144/3/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd June 1977

Date of last renewal: 23rd June 2002

10 DATE OF REVISION OF THE TEXT

August 2003