Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sodium pyrrolidone carboxylate 2.5 % w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Pyrrolidone Carboxylate 2.50 % w/w.

Excipients:
Contains cetostearyl alcohol 4%w/w.
Contains hydroxybenzoates (parabens) approximately 1%w/w: methyl (E218), ethyl (E214), propyl (E216) and butyl parahydroxybenzoates.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
Soft, white oil-in-water cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a lubricant and hydrating agent in the management of dry skin conditions such as certain types of eczema, ichthyosis and senile pruritus.

4.2 Posology and method of administration

Route of administration

For topical use only.

Adults, Children and the Elderly:

Apply liberally to the affected area and massage well into the skin.
Sodium pyrrolidone carboxylate 2.5 % w/w Cream may be used as often as required.

Sodium pyrrolidone carboxylate 2.5 % w/w Cream is especially beneficial when used immediately after washing or bathing, when the resultant warmth of the skin enhances absorption.

4.3 Contraindications

There are no contraindications except true hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

If there is aggravation of the condition consult the doctor.
The formulation is not designed for use as a diluent.

4.5 Interaction with other medicinal products and other forms of interactions

None known.

4.6 Fertility, pregnancy and lactation

Sodium pyrrolidone carboxylate 2.5 % w/w Cream is not contra-indicated in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Rarely a non serious allergic type reaction may be experienced, e.g. rash.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Not applicable, Sodium pyrrolidone carboxylate 2.5 % w/w Cream is for topical use only.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The combination of oils used in Sodium pyrrolidone carboxylate 2.5 % w/w Cream helps to lubricate and hydrate the skin. Moisture loss from the stratum corneum is reduced by the formation of an occlusive film by liquid paraffin on the surface of the skin. Isopropyl myristate, a fatty acid ester, is easily absorbed into the skin and helps to improve skin softness.

5.2 Pharmacokinetic properties

The combination of sodium pyrrolidone carboxylate and sodium lactate positively aids the hydration of the skin.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isopropyl Myristate
Liquid paraffin
Sodium Lactate
Cetomacrogol Emulsifying Wax (contains cetostearyl alcohol and Macrogol cetostearyl ether).
Myristyl Myristate
Macrogol Cetostearyl Ether
Hydroxybenzoates (Parabens): methyl (E218), ethyl (E214), propyl (E216) and butyl parahydroxybenzoates
Phenoxyethanol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Two years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original container.

6.5 Nature and contents of container

Sodium pyrrolidone carboxylate 2.5 % w/w Cream is packed in low density polythene tubes of 50 g and 100 g with a flush fitting cap. It is also available in polypropylene tubs containing 500 g with pump dispenser.

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

Any unused product or waste materials should be disposed of in accordance with the local requirements.

7 MARKETING AUTHORISATION HOLDER

Alliance Pharma (Ireland) Limited
United Drug Distributors, United Drug House
Magna Business Park, Magna Drive
Citywest
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA2325/007/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 16 May 2009

10 DATE OF REVISION OF THE TEXT

March 2019
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