Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sudocrem Antiseptic Healing Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

	% w/w
Zinc Oxide	15.29
Benzyl alcohol	0.39
Benzyl benzoate	1.02
Benzyl cinnamate	0.15
Wool Fat (Lanolin (hypoallergenic)	4.02

Excipients with known effect:
0.48% w/w Sodium Benzoate (E211), 0.33% w/w Propylene glycol (E1520) and 0.01% w/w Butylated hydroxyanisole (E320).
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
A smooth, homogeneous, white, water in oil cream with a lavender odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Sudocrem Antiseptic Healing Cream is indicated in the management of various dermatoses, including local skin reactions associated with incontinence.

4.2 Posology and method of administration

Posology
Apply a thin layer with suitable covering where necessary. Renew application as required. No distinction is required between indications or for adults, children and the elderly.

Method of administration
Topical cream for external use only.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

For external use only and should not be allowed to come into contact with the eyes and the mucous membranes.

If there is no improvement in the condition or aggravation thereof, the doctor should be consulted.

Excipient(s)
Sodium benzoate may cause non-immunologic immediate contact reactions by a possible cholinergic mechanism. Absorption through the immature skin of neonates is significant and may increase jaundice in this population.
Butylated hydroxyanisole may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.
Propylene glycol may cause skin irritation. This medicine should not be used in babies less than 4 weeks old with open wounds or large areas of broken or damaged skin (such as burns).

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

There are no known contraindications.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Side effects include local hypersensitivity occasionally.

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

No cases of overdose have been reported. If large amounts are swallowed accidentally, this may cause vomiting, diarrhoea, CNS stimulation and convulsions. Symptomatic treatment should be provided.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group, ATC code: D02AB Zinc products

Zinc oxide: a dermatological agent with astringent, soothing and protective properties.

Benzyl alcohol: a local anaesthetic with disinfectant properties.

Benzyl benzoate: an acaricide and has been used as a pediculicide, insect repellent and pharmaceutical solubilising agent.

Lanolin: resembles the sebaceous secretions of human skin.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified Water
Sodium Benzoate (E211)
Paraffin wax
Microcrystalline wax
Liquid Paraffin

Synthetic Beeswax
Sorbitan sesquioleate
Propylene glycol (E1520)
Citric acid
Butylated hydroxyanisole (E320)
Linalyl acetate
Lavender Fragrance

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Polypropylene jar: 3 years
Plastic tube: 2 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

60g, 125g, 250g and 400g polypropylene pots closed with polyethylene tamper evident caps

45g, 75g, 150g, 300g and 425g polypropylene pots closed with polyethylene tamper evident caps with a hinge

30 g COEX HDPE/LDPE 70:30 plastic tubes with flip top caps covered with a clear tamper evident plastic sleeve

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 medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Norton Waterford
T/A IVAX Pharmaceuticals Ireland
Unit 301
IDA Industrial Park
Cork Road, Waterford
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0436/054/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1978

Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

July 2023