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
Lanolin (hypoallergenic)	4.02

Excipient(s) with known effect

Sodium benzoate	0.48% w/w

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsified water in oil cream

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

In the treatment of:

1. Napkin rash
2. Eczema
3. Bedsores
4. Acne
5. Minor burns
6. Surface wounds
7. Sunburn
8. Chilblains

4.2. Posology and method of administration

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

Topical cream for external use only.

4.3. Contraindications

Hypersensitivity to any of the ingredients.

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.

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Excipient

Sodium benzoate may cause local irritation and may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

4.5. Interactions with other medicinal products and other forms of interaction

None known.

4.6. Fertility, pregnancy and lactation

There are no known contraindications.

4.7. Effects on Ability to Drive and Use Machines

Not applicable.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9. Overdose

No case of overdose has 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

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. It is a constituent of many natural balsams and is one of the principal esters of Peru Balsam.
Benzyl cinnamate	this is the other principal ester of Peru Balsal BPC 1973. It is synthetised from benzyl alcohol and cinnamic acid which has antibacterial and antifungal properties. Peru Balsam is categorised as having a mild antiseptic action because of cinnamic acid and its derivatives present.
Lanolin	resembles the sebaceous secretions of human skin. The grade (hypoallergenic) used is manufactured so as to exclude many sensitising substances present in the lanolin.

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
Paraffin wax
Microcrystalline wax
Heavy Liquid Paraffin
Synthetic Beeswax
Sorbitan sesquioleate
Propylene glycol
Antioxidant (Formulation consisting of Butylated hydroxyanisole (BHA),
Citric acid and
Propylene Glycol)
Linalyl acetate
Lavender

6.2. Incompatibilities

None known.

6.3 Shelf life

Not exceeding 3 years from date of manufacture.

6.4. Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

60g, 125g, 175g, 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

15g polypropylene jars with propylene caps

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

6.6. Special precautions for disposal

Not applicable.

7. MARKETING AUTHORISATION HOLDER

Teva UK Limited,
Ridings Point,
Whistler Drive,
Castleford,
WF10 5HX,
United Kingdom.

8. MARKETING AUTHORISATION NUMBER(S)

PL 00289/2299

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

5 March 2004

10 DATE OF REVISION OF THE TEXT

04/04/2023