

Product Summary

- Name of Product**
SUDOCREM ANTISEPTIC HEALING CREAM.
- Qualitative and Quantitative Composition of the active ingredients**

	%w/w		%w/w
Zinc Oxide, PhEur	15.25	Benzyl Alcohol, BP	0.39
Benzyl Benzoate, BP	1.01	Benzyl Cinnamate	0.15
Lanolin (hypoallergenic)	4.00		
- Pharmaceutical Form**
Emulsified water in oil cream.

Clinical Particulars

- Therapeutic Indications**
In the treatment of:

1. Napkin rash	4. Acne	7. Sunburn
2. Eczema	5. Minor burns	8. Chilblains
3. Bedsores	6. Surface wounds	
- 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.
- Contra-indications**
Hypersensitivity to any of the ingredients.
- 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.
- Interactions**
None known.
- Pregnancy and Lactation**
There are no known contra-indications
- Effects on Ability to Drive and Use Machines**
Not applicable.
- Undesirable Effects**
Side effects include local hypersensitivity occasionally.
- Overdose**
No cases of overdoses have been reported. If large amounts are swallowed accidentally, this may cause vomiting, diarrhoea, CNS stimulation and convulsions. Symptomatic treatment should be provided.

Pharmacological Properties

- 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.

Handwritten: Benzyl Cinnamate
Benzyl Cinnamate

this is the other principal ester of Peru Balsam BPC 1973. It is synthesised 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 (hypoallergenic) resembles the sebaceous secretions of human skin. The grade used is manufactured so as to exclude many sensitising substances present in the lanolin.

- Pharmacokinetic Properties**
Not applicable.
- Pre-clinical Safety Data**
Not applicable.

Pharmaceutical Particulars

- List of Excipients**

Purified water	Heavy liquid paraffin	Embanox 4
Sodium benzoate	Synthetic beeswax	Linalyl acetate
Paraffin wax	Sorbitan sesquileate	Lavender
Microcrystalline wax	Propylene glycol	
- Incompatibilities**
None known.
- Shelf Life**
Not exceeding 5 years from date of manufacture.
- Special Precautions for Storage**
No special precautions for storage.
- Nature and Contents of Container**

(a) polypropylene jars with polyethylene tamper-evident caps	Pack size (g)
(b) polypropylene jar with polyethylene cap	60, 125, 250, 400
(c) aluminium or laminated plastic aluminium tubes with aluminium membrane and plastic cap	15, 25 30
- Instructions for Use/Handling**
Not applicable.

Administrative Data

- Marketing Authorisation Holder**
Tosara Products (UK) Limited, PO Box 20, Liverpool, L18 9XS, UK.
- Marketing Authorisation Number**
PL 3430/0001R.
- Date of approval/revision of SPC**
Revision September 1996.
- Legal Category**
GSL.