SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Siopel Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Cetrimide	0.3% w/w
Dimeticone 1000	10% w/w

3 PHARMACEUTICAL FORM

A smooth, white homogeneous cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

An effective water repellent barrier cream with antiseptic properties, useful whenever the skin needs to be protected from water-soluble irritants.

4.2 Posology and method of administration

Wash and dry the skin. Apply the cream sparingly and massage well into the skin. Apply three to five times daily for three to four days then once or twice daily.

4.3 Contraindications

Siopel cream is contraindicated for patient who have previously shown a hypersensitivity reaction to cetrimide preparations.

4.4 Special warnings and precautions for use

For topical application only. Keep out of the eyes and avoid contact with the brain, meninges or middle ear. Do not use in body cavities or as an enema.

Do not use on skin that is acutely inflamed or weeping, or before the skin has been cleansed of contaminating irritants.

Siopel cream contains Arachis oil (peanut oil) and should not be applied by patients known to be allergic to peanut. As there is a possible relationship between allergy to peanut and allergy to Soya, patients with Soya allergy should also avoid Siopel cream.

If Siopel cream is used as a barrier cream on nipples by nursing mothers consideration must be given to the possibility of allergic reaction in infants with known or suspected allergies to peanut or Soya.

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.

4.5 Interaction with other medicinal products and other forms of interaction

None have been reported or are known.

4.6 Fertility, pregnancy and lactation

There is no evidence of any adverse effects on the foetus arising from the use of Siopel cream during pregnancy and therefore no special precautions are recommended.

Siopel cream contains Arachis oil (peanut oil) and should not be applied to nipples prior to breast feeding if the infant has known or suspected hypersensitivity to peanut or Soya.

4.7 Effects on ability to drive and use machines

None have been reported or are known.

4.8 Undesirable effects

Irritative skin reactions can occasionally occur and hypersensitivity to cetrimide preparations has been reported, usually developing after repeated applications, but is rare. Should such reactions occur, stop application of the product.

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

4.9 Overdose

It seems unlikely that systemic toxicity will occur from accidental ingestion of the cream. However, in the event of large quantities being swallowed, carry out gastric lavage with milk, raw egg, gelatin or mild soap and apply supportive measure as appropriate. Do not induce vomiting.

Central paralysis cannot be countered by curare antagonists or CNS stimulants but sympathomimetec drugs have been given.

Mechanically assisted ventilation with oxygen may be necessary. Persistent convulsions may be controlled with cautious doses of diazepam or a short-acting barbiturate. Do not give alcohol in any form.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Siopel cream is a topical agent for application to intact skin only, and is not intended to be administered by any other route.

Dimeticone 1000 is strongly substantive, binding firmly to the skin surface. There is no evidence of percutaneous absorption and in common with other silicone fluids, is considered to be physiologically inert. There are, as a consequence, no general pharmacological or pharmacokinetic studies available on dimeticone.

Studies with cetrimide have shown it to be active against a wide range of vegetative bacteria, both Gram positive and Gram negative, including *Staph. aureus* the commonest cause of infection in wounds and burns. Certain Gram negative bacteria, particularly strains of *Pseudomonas* and *Porteus* remain the least susceptible of the pathogenic bacteria to cetrimide, requiring a higher concentration than other species to produce an effective kill. Cetrimide is cationic in nature, binding strongly to skin and other tissues thus absorption is negligible.

5.2 Pharmacokinetic properties

Dimeticone 1000 – see section 5.1

Cetrimide:- Isomaa has studied the absorption, distribution and excretion of orally administered ^{14}C-labelled cetrimide in female rats. Approximately 80% of the dose of radioactivity was found in the gastro-intestinal tract 8 hours after administration. Only small amounts were found in the blood plasma and approximately 2% was excreted in the bile during the 12 hours after treatment. The low levels of radioactivity in the serum and bile, together with the large amounts of the antiseptic found in the gastro-intestinal tract, indicate poor intestinal absorption of cetrimide. Only small amounts of radioactivity were found in the liver, kidneys, spleen, heart, lungs and skeletal muscle, and the tissue radioactivity decline rapidly, only traces being found in the tissues 4 days after administration. Within 3 days of ingestion, 92% of the administered radioactivity had been excreted in the faeces and 1% in the urine. No radioactivity was found in the expired CO_2 collected during day 1 after administration. Thin-layer chromatography of bile and urine samples indicated that cetrimide was metabolised to some extent in the rat.

5.3 Preclinical safety data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Arachis Oil
Butylated Hydroxytolulene
Cetostearyl Alcohol
Anhydrous Citric Acid
Methyl Parahydroxybenzoate
Purified Water

6.2 Incompatibilities

Cetrimide is incompatible with soap and other anionic agents.

6.3 Shelf life

4 years

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Aluminium tube (50g)

6.6 Special precautions for disposal

For topical application only. See also section 4.4

7 MARKETING AUTHORISATION HOLDER

Derma UK Ltd
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8 MARKETING AUTHORISATION NUMBER(S)

PL 19876/0010

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23 January 2003 / 16/11/2005

10 DATE OF REVISION OF THE TEXT

02/09/2019