

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cepton Medicated Lotion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: Chlorhexidine Gluconate 0.1 % w/v (incorporated as Chlorhexidine Gluconate Solution BP 0.5 % v/v)

For excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Cutaneous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

An aid in the treatment of spots and acne.

4.2 Posology and method of administration

Apply morning and night as follows:

- After washing - Moisten a cotton wool pad with Medicated Lotion and apply to the face, particularly around the nose, forehead and chin. Do not rinse off.
- After shaving - Pour Medicated Lotion into the hands and splash onto the face
- During the day - Moisten a pad or tissue with Medicated Lotion and apply to oily areas to cleanse, ton and remove greasy patches as they appear.

4.3 Contraindications

None known.

4.4 Special warnings and precautions for use

For external use only
Keep all medicines away from children
Keep out of the eyes
Flammable

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

No known restrictions.

4.7 Effects on ability to drive and use machines

The ability to drive or use machines is not affected.

4.8 Undesirable effects

None known.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chlorhexidine is an effective antiseptic with a wide range of activities against micro-organisms, including gram positive and gram negative bacteria, fungi and viruses.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Brilliant Blue (E133)
Ethanol
Macrogol
Perfume compound 8411
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Opaque high density polyethylene bottle with pierced polyethylene shive and urea formaldehyde cap.

Pack sizes: 25, 150 ml

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Eastern Pharmaceuticals Limited,
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Middlesex TW7 6NA,
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8 MARKETING AUTHORISATION NUMBER

PA 0739/003/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 June 1991

Date of last renewal: 26 June 2001