

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cepton Medicated Skin Wash

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: Chlorhexidine Gluconate 1.0 % w/v

3 PHARMACEUTICAL FORM

Cutaneous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For daily use in the treatment and prevention of spots and acne.

4.2 Posology and method of administration

For topical use only

Apply morning and night as follows:

Wash hands and face

Wash with undiluted medicated skin wash, then rinse. Repeat.

For maximum effect, leave second wash on skin for one minute before rinsing.

4.3 Contraindications

None known.

4.4 Special warnings and precautions for use

For external use only

Keep all medicines away from children

If skin irritation occurs stop using and talk to your doctor

Keep out of the eyes and ears

Treat accidental splashes into the eyes by washing out immediately with water and seek medical advice

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

If swallowed, wash out the mouth and drink plenty of milk or water; seek medical advice.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chlorhexidine is an effective antiseptic with a wide range of activity 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

Polyoxyethylene polyoxypropylene block co-polymer
Lauryl dimethyl amine oxide
Ponceau 4R (E124)
Isopropyl alcohol
Perfume
D-gluconolactone
Sodium hydroxide
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

High density polyethylene bottle with screw cap closure.
Pack sizes: 50, 100, 150 and 250 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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Isleworth,
Middlesex TW7 6NA,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER

PA 0739/003/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 June 1991

Date of last renewal: 26 June 2001