

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cepton Medicated Clear Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: Chlorhexidine Gluconate 0.5 % w/w (incorporated as Chlorhexidine Gluconate Solution BP 2.5 % v/w)

For excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

An aid in the treatment 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, apply a thin coating of the gel to the affected area and work in thoroughly.

4.3 Contraindications

None known.

4.4 Special warnings and precautions for use

For external use only

Keep all medicines away from children

If no improvement occurs or skins irritation follows, stop using and talk to your doctor

Keep out of the eyes.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

No use in pregnancy warning is required.

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 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

Ethanol
Polyoxyethylated castor oil hydrogenated
Hydroxyethyl cellulose
Sodium acetate
Perfume
Water

6.2 Incompatibilities

None.

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

Internally lacquered collapsible aluminium tube with HDPE screw cap closure.

Pack sizes 30 g.

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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8 MARKETING AUTHORISATION NUMBER

PA 0739/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20 August 1991

Date of last renewal: 20 August 2001

10 DATE OF REVISION OF THE TEXT

December 1999