

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Acnemed Skin Wash 1% w/v Lotion

Cepton Medicated Skin Wash

Chlorhexidine Gluconate 1% w/v Lotion

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Active ingredient: Chlorhexidine Gluconate 1.0% w/v.

### **3 PHARMACEUTICAL FORM**

Lotion

### **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**

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 the skin for one minute before rinsing

#### **4.3 Contraindications**

Known hypersensitivity to any of the constituents.

#### **4.4 Special warnings and precautions for use**

For external use only.

Frequently repeated topical application on the same site could theoretically lead to skin irritation.

Consult your doctor if symptoms persist.

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.

Keep all medicines out of the reach and sight of children.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Chlorhexidine is incompatible with anionic agents.

#### **4.6 Fertility, pregnancy and lactation**

The product is not contra-indicated during pregnancy and lactation. However, as with all medicines during pregnancy, caution should be exercised. Consult your doctor or pharmacist before use.

#### **4.7 Effects on ability to drive and use machines**

The ability to drive or use machines is not affected.

#### **4.8 Undesirable effects**

Rarely local irritation, rashes and other skin reactions such as contact dermatitis may occur.

Anaphylactic allergic reactions have also been reported but are very rare.

##### **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 at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

#### **4.9 Overdose**

Accidental ingestion: Chlorhexidine taken orally is poorly absorbed. Systemic effects are unlikely even if large amounts are ingested. However, gastric lavage may be advisable using milk, raw egg, gelatin or mild soap. Employ supportive measures as appropriate.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotheapeutic group: Dermal Antiseptic Group

ATC Code: D08AC02

Chlorhexidine is an effective antiseptic with a wide range of activity against microorganisms, including gram positive and gram negative bacteria, fungi and viruses.

### **5.2 Pharmacokinetic properties**

Because of its cationic nature, chlorhexidine binds strongly to skin, mucosa and tissues and is thus very poorly absorbed and percutaneous absorption, if it occurs at all, is insignificant.

The antiseptic ingredients are in intimate contact with the skin, and as they are in solution, their availability is optimal.

### **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 (E 124)

Isopropyl alcohol

Perfume

D -gluconolactone

Sodium hydroxide

Water

### **6.2 Incompatibilities**

None

**6.3 Shelf life**

3 years

**6.4 Special precautions for storage**

Store below 25°C.

**6.5 Nature and contents of container**

High density polyethylene bottle with screw cap closure. Pack sizes: 10ml, 25ml, 50ml, 100ml, 150ml and 250ml.

**6.6 Special precautions for disposal**

Medicines should be kept out of the reach of children.

**7 MARKETING AUTHORISATION HOLDER**

Boston Healthcare Limited

Unit 6, Navigation Court

Calder Park

Wakefield

West Yorkshire WF2 7BJ

United Kingdom

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 39974/0004

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

27<sup>th</sup> January 2005

## **10     DATE OF REVISION OF THE TEXT**

09/03/2017