

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Chlorhexidine Acetate BP 0.02% w/v Irrigation solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Chlorhexidine Acetate.

Quantitative Composition

Per litre: Chlorhexidine Acetate 0.2 g

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Irrigation solution.

A clear, colourless, sterile aqueous irrigation solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a disinfectant for topical irrigation of wounds and burns.

For disinfection of respirators.

4.2 Posology and method of administration

Dosage

The dosage of the product is determined by the individual patient's requirements.

Administration

For topical use only.

4.3 Contraindications

This solution should not come into contact with the brain meninges, perforated ear drum or eyes. This solution is not recommended for bladder-irrigation. Use in patients with known hypersensitivity to chlorhexidine. This solution is not for use in abdominal cavities, unless under supervision of a specialist.

4.4 Special warnings and precautions for use

This solution should not be taken orally. This solution is not for intravenous administration. Accidental ingestion should be treated with a stomach lavage consisting of milk, egg white, gelatine or mild soap. Idiosyncratic reactions to chlorhexidine acetate BP have been reported.

This product should only be used in specialist units familiar with the appropriate selection of patients.

4.5 Interaction with other medicinal products and other forms of interaction

The action of chlorhexidine is reduced by an alkaline pH, the presence of organic matter, anionic detergents and tannins. Effect of chlorhexidine will be inactivated on contact with soap, blood. (Following SPC Travahex 0.5%).

4.6 Pregnancy and lactation

This product should not be used during pregnancy unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Very occasionally the following reactions have been noted when chlorhexidine containing irrigating solutions have been used intravesically, intravaginally, or topically on traumatised skin: hypotension, paraesthesia, dyspnoea, tachycardia, cold sweat, generalised erythema, urticaria and loss of consciousness.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Therapeutic group: B05D

This solution is intended for use as an external irrigating solution as an effective disinfectant against Gram-positive and Gram-negative bacteria.

5.2 Pharmacokinetic properties

Given the method for use of the solution, absorption through the skin is minimal, no significant levels being found in blood.

5.3 Preclinical safety data

Given its topical application, the potential toxicity of this solution is very low.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections
Acetic Acid

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Unopened: 2 years.

Opened: For single-use only.

6.4 Special precautions for storage

Do not store above 25°C.

Store in the original container.

6.5 Nature and contents of container

The product will be supplied in High Density Polyethylene single-use containers of the following sizes: 100ml, 500ml and 1000ml.

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

Do not use unless solution is clear and the container is undamaged.

7 MARKETING AUTHORISATION HOLDER

Baxter Healthcare Ltd.,
Caxton Way,
Thetford,
Norfolk,
IP24 3SE,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER

PA 0167/010/009

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 1st April 2003

10 DATE OF REVISION OF THE TEXT

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