Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Chlorhexidine Acetate BP 0.02 % w/v for Irrigation, 250 ml.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine acetate 0.02% w/v.

3 PHARMACEUTICAL FORM

Sterile cutaneous irrigation solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a disinfectant for topical irrigation of wounds or burns.

For disinfection of respirators.

4.2 Posology and method of adminstration

4.2.1. Dosage

The dosage is dependant upon the age, weight and clinical condition of the patient

4.2.2. Administration

For topical use only.

4.3 Contraindications

This solution must 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, not for use in abdominal cavities, unless under supervision of a specialist.

4.4 Special warnings and special 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.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable.

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

Not applicable.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections
Acetic acid

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

24 months.

6.4 Special precautions for storage

Do not store above 25^{o}C.

Keep container in the original carton.

6.5 Nature and contents of container

250 ml high density polyethylene single use containers.

6.6 Instructions for use and handling

Do not use unless solution is clear and the container is undamaged.
Discard any unused portion.

7 MARKETING AUTHORISATION HOLDER

Baxter Healthcare Ltd.
Caxton Way
Thetford
Norfolk
IP24 3SE
England

8 MARKETING AUTHORISATION NUMBER

PA 167/10/15

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th September 1986

Date of last renewal: 30th September 2001

10 DATE OF REVISION OF THE TEXT

December 2001