Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Hibitane 5% w/v concentrate for cutaneous solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine gluconate 5% w/v (incorporated as Chlorhexidine Gluconate Solution).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for cutaneous solution
Clear red liquid with an odour of lavender.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Hibitane 5% w/v Concentrate is an antimicrobial agent for general antiseptic purposes.

4.2 Posology and method of administration

Method of Preparation	**Concentration of active ingredient required (chlorhexidine gluconate)**	**Use**
10ml made up to 1 litre with water (1 in 100)	1 in 2,000 (0.05%) aqueous	Swabbing in obstetrics, wounds and burns*. Storage of sterile instruments.
10ml with 15ml water made up to 100ml with 95 % alcohol (1 in 10) (or any multiple that gives 1 in 10)	1 in 200 (0.5 %) in 70 % alcohol	Preoperative skin disinfection. Emergency instrument disinfection (2 minutes immersion) – (excluding endoscopes containing cemented glass components).

**sterilise the dilution by autoclaving at 115º – 116ºC for 30 minutes or 121º – 123ºC for 15 minutes*

4.3 Contraindications

Hibitane preparations are contraindicated for patients who have previously shown a hypersensitivity reaction to chlorhexidine. However, such reactions are extremely rare.

Use in contact with the brain, meninges, middle ear or eyes.

4.4 Special warnings and precautions for use

For external use only.

Dilute before use.

Not for injection. Do not use in body cavities.

The concentrated solution is irritant to eyes and mucous membranes. Keep all solutions out of the eyes. If solutions do come into contact with the eyes, wash out promptly and thoroughly with water.

Prolonged skin contact with alcoholic solutions should be avoided. Allow to dry before proceeding.

Solutions applied to wounds, burns or broken skin should be sterile.

Syringes, needles or instruments which have been immersed in Hibitane solutions should be thoroughly rinsed in sterile water or saline before use.

Cases of burning have been reported when electrosurgical units have been used after alcohol-based antiseptics have been applied, due to residual quantities of the product being present. After the operation site has been prepared, it is therefore advisable to ensure that the product has dried completely and that there are no residual amounts of product that could have run, particularly into folds of skin or onto the table cover.

4.5 Interaction with other medicinal products and other forms of interaction

Hypochlorite bleaches may cause brown stains to develop in fabrics which have previously been in contact with preparations containing chlorhexidine.

Hibitane is incompatible with soap and other anionic agents.

4.6 Fertility, pregnancy and lactation

No special precautions required.

4.7 Effects on ability to drive and use machines

No precautions required.

4.8 Undesirable effects

Irritative skin reactions can occasionally occur. Idiosyncratic skin reactions and generalised allergic reactions to chlorhexidine, which in very few cases can lead to anaphylactic shock, have been reported. These were rare in relation to the large usage of chlorhexidine.

4.9 Overdose

Accidental ingestion:

Chlorhexidine taken orally is poorly absorbed. Treat with gastric lavage with milk, raw egg, gelatin or mild soap. Employ supportive measures as appropriate.

Accidental intravenous infusion:

Blood transfusion may be necessary to counteract haemolysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chlorhexidine is effective against a wide range of gram-negative and gram-positive vegetative bacteria, yeasts, dermatophyte fungi and lipophilic viruses. It is inactive against bacterial spores except at elevated temperatures.

5.2 Pharmacokinetic properties

Because of its cationic nature, chlorhexidine binds strongly to skin, mucosa and other tissues and is thus poorly absorbed. No detectable blood levels have been found in man following oral use and percutaneous absorption, if it occurs at all, is insignificant.

5.3 Preclinical safety data

Chlorhexidine is an agent in which extensive clinical experience has been obtained. All relevant information for the prescriber is provided elsewhere in the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carmosine (E122)
d - Gluconolactone
Isopropyl Alcohol
Linalyl Acetate
Nonylphenol/ethylene oxide condensate
Purified Water

6.2 Incompatibilities

Chlorhexidine is incompatible with soap and other anionic agents.
Do not use diluted solutions to disinfect catheters intended for use in peritoneal dialysis, as precipitation and consequent loss of activity may result.

6.3 Shelf life

Unopened: 4 years.
Sterile dilutions: In order to further minimise the risk of mircobial contamination, it is recommended that sterile dilutions be made only when needed and that any unused diluted solution be discarded.
Aqueous dilutions: of Hibitane used for instrument storage should contain 0.1% w/v sodium nitrite to inhibit metal corrosion. Such solutions must be changed every 7 days.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Square HDPE container with tamper evident HDPE screw cap (5 liters).

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

Dilute with freshly distilled water, tap water of an acceptable bacteriological standard or alcohol (ethanol, Industrial Methylated Spirit or isopropanol).

As a precaution against bacterial contamination aqueous stock solutions should contain at least 4% v/v of isopropanol or 7% v/v of ethanol which may be denatured (for example, Industrial Methylated Spirit).

As cork may protect certain Gram-negative organisms for the action of antiseptics, ‘Hibitane’ solutions must be stored in bottles with glass, plastic or rubber closures.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 1218/3/1

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