**HIBICET** Hospital Concentrate is an antimicrobial preparation with cleansing properties for general antiseptic purposes.

### Method of preparation

**Dilution**

1. **Use**
   - 10 ml made up to 1 litre with water
   - 1 in 100 (1%)

2. **Aqueous**
   - Cleansing/antiseptic treatment of wounds and burns. Swabbing in obstetrics, gynaecology and urology. Cleansing/disinfectant soak for used metal instruments. Clean instrument disinfection where no means of sterilisation is available (30 minutes immersion).
   - Cleansing/disinfection of equipment, furniture and fittings in the vicinity of the patient.
   - Storage of clinical thermometers and sterile instruments.
   - 35 ml made up to 1 litre with water
   - 1 in 30 (approx.)
   - Aqueous

3. **Liquid**
   - 1 in 100 (1%)

4. **Dilution**
   - 1 in 30 (approx.)
   - In 70% Alcohol

### Use

- **Rapid skin antisepsis before operation and other invasive procedures.**
- **Disinfection of clean instruments and equipment (2 minutes’ immersion).**
- **Disinfection of clinical thermometers.**
- **Swabbing in obstetrics, gynaecology and urology.**
- **Cleansing/antiseptic treatment of wounds and burns where greater cleansing/antisepsis is required.**
- **Cleansing/disinfection soaks for soiled instruments.**
- **35 ml with 200 ml water made up to 1 litre with 95% alcohol**
- **1 in 30 (approx.)**
- In 70% Alcohol

### 4.3. Contraindications

**HIBICET** preparations are contraindicated for patients who have previously shown a hypersensitivity reaction to either chlorhexidine or cetrimide. However, such reactions are extremely rare.

### 4.4. Special Warnings and Precautions for Use

For external use only. Dilute before use. Avoid contact with the brain, meninges and ears. Not for injection. Do not use in body cavities or as an enema. The concentrated solution is irritant to eyes and mucous membranes. Keep all solutions out of the eyes. If solutions do come into contact with eyes, wash out promptly and thoroughly with water. If concentrated cetrimide solutions come into contact with the skin, rinse 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 sterilised according to B.P. recommendations. Syrings and needles which have been immersed in **HIBICET** solutions should be thoroughly rinsed in sterile water or saline before use. **HIBICET** solutions may affect glass cement and therefore are not suitable for the disinfection of endoscopes.

### 4.5. Interactions with other Medicinal Products and other Forms of Interaction

See section 6.2.

### 4.6. Pregnancy and Lactation

There is no evidence of any adverse effects on the foetus arising from the use of **HIBICET** Hospital Concentrate during pregnancy. Therefore no special precautions are recommended.

### 4.7. Effects on Ability to Drive and Use Machines

None have been reported or are known.

### 4.8. Undesirable Effects

Irritative skin reactions can occasionally occur and rare hypersensitivity to cetrimide preparations, usually developing after repeated application, has been reported. There have been rare reports of severe burn-like reactions to concentrated cetrimide solutions. Should such a reaction occur, treat as a chemical burn. Generalised allergic reactions to chlorhexidine have also been reported but are extremely rare. In all these cases, stop application of the product.

### 4.9. Overdose

This has not been reported. Accidental oral or rectal administration if the product is swallowed give large quantities of milk, raw egg, gelatin or mild soap. Avoid vomiting or lavage if it is believed that a concentrated solution has been ingested. Central paralysis cannot be countered by curare antagonists or CNS stimulants but sympathomimetic drugs have been given. Mechanically assisted ventilation with oxygen may be necessary. Persistent convulsions may be controlled with cautious doses of diazepam or a short-acting barbiturate. Do not give alcohol in any form.

**Accidental intravenous infusion** Mass haemolysis can occur which will require blood transfusion.

**Accidental intra-uterine administration** Introduction into the uterus can lead to haemolysis and pulmonary embolism.

### 5. Pharmaceutical Properties

#### 5.1. Pharmacodynamic Properties

**HIBICET** Hospital Concentrate is a topical antiseptic for external use only and is not intended to be administered orally or parenterally. The active agents, chlorhexidine gluconate and cetrimide are strongly cationic, binding to skin, mucosa and exposed tissues, thus percutaneous absorption is poor. There are, as a consequence, no general pharmacological studies available on the effects of **HIBICET** Hospital Concentrate or other topically administered chlorhexidine/cetrimide formulations. If chlorhexidine is systemically absorbed there is no evidence of metabolic cleavage of the drug, however, animal studies suggest that systemically absorbed cetrimide may be metabolised to some extent.

Both active agents have a broad spectrum of antimicrobial activity and are bacteriostatic at low concentrations whilst at higher concentrations their activity is rapidly bactericidal. They are both active against dermatophytic fungi (including the yeast C. Albicans) and enveloped viruses such as HIV.

#### 5.2. Pharmacokinetic Properties

Percutaneous absorption of the active agents in **HIBICET** Hospital Concentrate is poor. Studies in animals using 14C-Labelled cetrimide have shown that even after oral dosing only small amounts were found in the blood plasma and approximately 2% was excreted in the bile during the first 12 hours after treatment: only small amounts of radioactivity were found in the liver, kidneys, spleen, heart, lungs and skeletal muscle and tissue radioactivity declined rapidly.

Similarly, attempts to detect percutaneous absorption of chlorhexidine gluconate in man have shown that, if it occurs at all, the level is exceedingly small and insignificant – the limit of detection used being of the order of 0.005 mg/litre.

Furthermore, it is very unlikely that the pharmacokinetic properties of either chlorhexidine gluconate or cetrimide will be altered significantly in special situations, such as hepatic failure, renal failure, treatment of children, the elderly, in pregnancy or nursing mothers.

### 5.3. Pre-clinical Safety Data

Chlorhexidine and cetrimide are drugs on 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

- Benzyl benzolate: Industrial methylated spirit; D-glucosamine; Isopropyl alcohol; Liquid deodoriser; Purified water; Sodium hydroxide; Sunset Yellow FCF (E110); Terpineol.

#### 6.2. Incompatibilities

Hypochlorite bleaches may cause brown stains to develop in fabrics which have previously been in contact with preparations containing chlorhexidine. Chlorhexidine and cetrimide are incompatible with soap and other anionic agents.

#### 6.3. Shelf Life

4 years.

#### 6.4. Special Precautions for Storage

Do not store above 30 °C.

#### 6.5. Nature and Contents of Container

While HDPE bottle with a white tamper evident HDPE screw cap.

#### 6.6. Instruction for Use, Handling and Disposal

Dilute before use. Dilute with tap water of an acceptable bacteriological standard or alcohol (ethanol, industrial methylated spirits or isopropanol). Add diluent slowly to prevent excessive foaming. 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 (i.e. industrial methylated spirit). **HIBICET** solutions used for instrument storage should contain 0.4% w/v sodium nitrite to inhibit metal corrosion. Such solutions must be changed every 7 days. Prolonged immersion of rubber appliances in **HIBICET** solutions is undesirable. As cork may protect certain gram-negative organisms from the action of antisepsics, **HIBICET** solutions must be stored in bottles with glass, plastic or rubber closures.