

IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA1218/004/001

Case No: 2068374

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Regent Medical Overseas Limited

Two Omega Drive, River Bend Technology Centre, Irlam, Manchester M44 5BJ, United Kingdom

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Hibicet Hospital Concentrate for cutaneous solution

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **30/10/2009**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Hibicet Hospital Concentrate for cutaneous solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine gluconate 1.5% w/v
(equivalent to 7.5% v/v chlorhexidine gluconate 20% solution)

Cetrimide 15% w/v
(equivalent to 37.5% w/v strong cetrimide solution 40% w/v)

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Concentrate for cutaneous solution.
A clear, deep orange perfumed aqueous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

'Hibicet' Hospital Concentrate is an antimicrobial preparation with cleansing properties for general antiseptic purposes.

4.2 Posology and method of administration

Apply as required in aqueous or alcoholic dilutions of 1 in 30 to 1 in 100.

4.3 Contraindications

'Hibicet' Hospital Concentrate preparations are contra-indicated for patients who have previously shown a hypersensitivity reaction to either chlorhexidine or cetrimide.

Avoid contact with brain, meninges, middle ear, eyes or as an enema. Do not use in body cavities. Do not use as injection.

4.4 Special warnings and precautions for use

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. If there is evidence of irritation, discontinue use.

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.

4.5 Interaction with other medicinal products and other forms of interaction

None stated

4.6 Pregnancy and lactation

No special precautions are required.

4.7 Effects on ability to drive and use machines

No precautions are required.

4.8 Undesirable effects

Irritative skin reactions (local irritation and burn like reactions) can occasionally occur.

In all these cases, stop application of the product.

4.9 Overdose

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: Massive haemolysis can occur which will require blood transfusion.

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

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.

Studies with cetrimide have shown it to be active against a wide range of vegetative bacteria, both Gram positive and Gram negative, including *Staph. aureus* the commonest cause of infection in wounds and burns. Certain Gram negative bacteria, particularly strains of *Pseudomonas* and *Proteus* remain the least susceptible of the pathogenic bacteria to cetrimide, requiring a higher concentration than other species to produce an effective kill.

5.2 Pharmacokinetic properties

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

Cetrimide is also cationic in nature, binding strongly to skin and other tissue, and thus absorption is negligible.

5.3 Preclinical 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

Industrial methylated spirit 74 OP
Isopropyl alcohol
Terpineol
Liquid deodoriser
Benzyl benzoate
Sunset yellow FCF (E110)
Purified water
d-gluconolactone
Sodium hydroxide

6.2 Incompatibilities

Chlorhexidine and cetrimide are incompatible with soap and other anionic agents.

6.3 Shelf Life

Four years.

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

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

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 before use.

Dilute with tap water of an acceptable bacteriological standard or alcohol (ethanol, Industrial Methylated Spirit 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' Hospital Concentrate solutions used for instrument storage should contain 0.4% sodium nitrite to inhibit metal corrosion. Such solution must be changed every 7 days. Prolonged immersion of rubber appliances in 'Hibicet' Hospital Concentrate solutions is undesirable.

As cork may protect certain Gram-negative organisms from the action of antiseptics, 'Hibicet' Hospital Concentrate solutions must be stored in bottles with glass, plastic or rubber closures.

See also section 4.2 and 4.4.

7 MARKETING AUTHORISATION HOLDER

Regent Medical Overseas Limited
Two Omega Drive
River Bend Technology Centre
Irlam
Manchester M44 5BJ
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 1218/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983

Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

May 2009