IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA1218/002/001
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

Hibisol 0.5% w/v 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** until **29/05/2010**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Hibisol 0.5% w/v Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Gluconate 0.5% w/v
(incorporated as Chlorhexidine Gluconate Solution)

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution.

Clear, colourless, non-viscous solution having an odour of isopropyl alcohol

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

'Hibisol' is a rapid acting antimicrobial preparation for the disinfection of clean intact skin. It is used for pre-operative surgical hand disinfection, hand disinfection on the ward prior to aseptic procedures or after handling contaminated material, and for disinfection of patients' skin prior to surgery or other invasive procedures.

4.2 Posology and method of administration

Pre-operative surgical hand disinfection

Dispense 5ml of 'Hibisol' and spread thoroughly over both hands and forearms, rubbing vigorously. When dry, apply a further 5ml and repeat the procedure.

NB Before the first operation on a list or subsequently when hands are soiled, the hands should be cleansed and disinfected with an antiseptic/detergent handwash.

Antiseptic hand disinfection on the ward

Dispense 3ml of 'Hibisol' and spread thoroughly over the hands and wrists rubbing vigorously until dry.

NB If the hands are soiled, cleanse and dry before using 'Hibisol' or alternatively use an antiseptic/detergent handwash.

Disinfection of patients' skin

Prior to surgery, apply 'Hibisol' to a sterile swab and rub vigorously over the operation site for a minimum of two minutes. 'Hibisol' is also used for preparation of the skin prior to invasive procedures such as venepuncture.

4.3 Contraindications

'Hibisol' preparations are contra-indicated for patients who have previously shown a hypersensitivity reaction to chlorhexidine. However, such reactions are extremely rare.

4.4 Special warnings and precautions for use

For external use only. Hibisol is for topical use on the skin only and should not be applied by injection into the skin or administered by any means to tissues other than the skin.

Avoid contact with the brain, meninges and middle ear.

Not for injection into any area of the body or into the skin or into body or joint cavities.

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

Flammable. This preparation contains alcohol. When use is to be followed by diathermy do not allow pooling of the fluid to occur, and ensure that the skin and surrounding drapes are dry.

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

Hypersensitivity reactions to chlorhexidine-impregnated patches have been reported rarely when used in neonates.

4.5 Interaction with other medicinal products and other forms of interaction

See section 6.2.

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 can occasionally occur. Generalised allergic reactions to chlorhexidine have also been reported but are extremely rare.

4.9 Overdose

Accidental ingestion

‘Hibisol’ taken orally is poorly absorbed. Treat with gastric lavage using milk, raw egg, gelatin or mild soap avoiding pulmonary aspiration. Do not use apomorphine. Assist respiration if necessary and keep patient warm. Intravenous laevulose can accelerate alcohol metabolism. In severe cases, haemodialysis or peritoneal dialysis may be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chlorhexidine belongs to the “antiseptic and disinfectants” therapeutic group ATC code D08A C02. It 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 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.

5.3 Preclinical safety data

Chlorhexidine is a drug 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

Isopropyl alcohol
Cyclomethicone
Isopropyl isostearate
Purified water

6.2 Incompatibilities

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

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

HDPE bottle with plastic (urea) screw cap (250 ml, 500 ml).
Not all pack sizes may be marketed.

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

Flammable. *See also section 4.4.*

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA 1218/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30 May 1985

Date of last renewal: 30 May 2005

10 DATE OF REVISION OF THE TEXT

June 2006