

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Hibiscrub 4.0% w/v Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Gluconate 40 mg/ml (4.0% w/v).
(incorporated as Chlorhexidine Digluconate Solution).

Excipient with known effect

Herbacol 0.5 mg/ml, fragrance with 3-Methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one, Amyl cinnamal, Amylcinnamyl alcohol, Anisyl alcohol, Benzyl alcohol, Benzyl benzoate, Benzyl cinnamate, Benzyl salicylate, Cinnamal, Citral, Citronellol, Coumarin, d-Limonene, Eugenol, Farnesol, Geraniol, Hexyl cinnamaldehyde, Hydroxymethylpentyl-cyclohexenecarboxaldehyde, Isoeugenol, Lilial, Linalool, Methyl heptine carbonate, Oak moss and Tree moss.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Solution

A clear or slightly opalescent red aqueous detergent antiseptic solution with a characteristic citrus odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

'Hibiscrub' is an antimicrobial preparation for pre-operative surgical hand disinfection, antiseptic hand washing on the ward, pre-operative skin preparation for patients undergoing elective surgery and post-operative skin antisepsis for the patient.

4.2 Posology and method of administration

For external use only.

Pre-operative surgical hand disinfection

Wet the hands and forearms, apply 5 ml of 'Hibiscrub' and wash for one minute cleaning the fingernails with a brush or scraper. Rinse, apply a further 5 ml of 'Hibiscrub' and continue washing for a further two minutes. Rinse thoroughly and dry.

Antiseptic hand wash on the ward

Wet the hands and forearms, apply 5 ml of 'Hibiscrub' and wash for one minute. Rinse thoroughly and dry.

Pre-operative skin preparation for patients undergoing elective surgery

This involves two stages:

First phase (e.g. on ward): The patient may prepare himself by undertaking whole-body disinfection with 'Hibiscrub'.

On at least two occasions, usually the day before and the day of the operation, the patient, unless bedridden, should wash his whole body with 'Hibiscrub' in the bath or shower. 'Hibiscrub' should be used undiluted. Beginning with the face and working down the body, particular attention should be paid to the areas around the nose, armpits, umbilicus, groin and perineum. After washing these important sites, the whole body should be rinsed and washed again, starting with the hair and working downwards.

Finally the whole body should be rinsed and using a freshly laundered towel the entire body surface should be dried thoroughly.

Bedridden patients can be washed with 'Hibiscrub' using the standard bed-bath technique.

Alternatively, undiluted 'Hibiscrub' can be rubbed over the intended operation site and surrounding skin for 2 minutes using sterile gauze swab(s). Sufficient water, preferably sterile, is added to work up a lather.

Finally, the area is wiped clean and dried thoroughly with sterile swabs.

Three applications are made at suitable intervals throughout the day before operation.

Second stage (e.g. in theatre): The following procedure is recommended. With sterile gauze swabs wetted with 0.5% alcoholic 'Hibitane' solution, rub the operation site and surrounding skin thoroughly for two minutes and allow to dry.

Post-operative skin antisepsis for the patient

The patient washes his whole body, excluding the operation wound, in the bath or shower usually on the third day after operation using the procedure described above.

4.3 Contraindications

Known hypersensitivity to the product or any of its components, especially in those with a history of possible chlorhexidine-related allergic reactions (see sections 4.4 and 4.8).

4.4 Special warnings and precautions for use

Hibiscrub contains chlorhexidine. Chlorhexidine is known to induce hypersensitivity, including generalised allergic reactions and anaphylactic shock. The prevalence of chlorhexidine hypersensitivity is not known, but available literature suggests this is likely to be very rare. Hibiscrub should not be administered to anyone with a potential history of an allergic reaction to a chlorhexidine-containing compound (see sections 4.3 and 4.8).

Hibiscrub 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. In patients with head or spinal injuries or perforated ear drum, the benefit of use in pre-operative preparation should be evaluated against the risk of contact.

Reports of arachnoiditis have been received following accidental exposure to the meninges and/or contamination of equipment used for central neuraxial blockade with chlorhexidine. Therefore, if chlorhexidine is used for procedures, that pose a risk of exposure to the meninges, extra care must be taken to minimise the risk of contamination of equipment used.

When using to disinfect the skin prior to procedures where there is a risk of meningeal exposure, allow to dry before inserting needle.

Keep out of the eyes. If chlorhexidine solutions come into contact with the eyes, wash out promptly and thoroughly with water.

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

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

The use of chlorhexidine solutions, both alcohol based and aqueous, for skin antisepsis prior to invasive procedures has been associated with chemical burns in neonates. Based on available case reports and the published literature, this risk appears to be higher in preterm infants, especially those born before 32 weeks of gestation and within the first 2 weeks of life.

Remove any soaked materials, drapes or gowns before proceeding with the intervention.

Do not use excessive quantities and do not allow the solution to pool in skin folds or under the patient or drip on sheets or other material in direct contact with the patient. Where occlusive dressings are to be applied to areas previously exposed to Hibiscrub, care must be taken to ensure no excess product is present prior to application of the dressing.

4.5 Interaction with other medicinal products and other forms of interactions

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

4.6 Fertility, 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

Very Common ($\geq 1/10$); Common ($\geq 1/100$, $< 1/10$); Uncommon ($\geq 1/1,000$, $< 1/100$); Rare ($\geq 1/10,000$, $< 1/1,000$); Very rare ($< 1/10,000$); not known (cannot be estimated from the available data).

Skin and subcutaneous tissue disorders:

Frequency not known: Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticaria, skin irritation, and blisters.

Immune system disorders:

Frequency not known: Hypersensitivity including anaphylactic shock (see sections 4.3 and 4.4).

Injury, poisoning and procedural complications:

Frequency not known: Chemical burns in neonates

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2. Tel: +353 1 6764971 Fax: +353 1 6762517.

Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

4.9 Overdose

Accidental ingestion

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

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

Poloxamer 237
Isopropyl alcohol
Lauryl dimethyl amine oxide
Glycerol
Macrogol-7 Glycerol Cocoate
Gluconolactone
Herbacol
Ponceau 4R (E124)
Purified water
Sodium hydroxide (for pH-adjustment)

6.2 Incompatibilities

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. Store in the original package.

6.5 Nature and contents of container

- (i) White high density polyethylene (HDPE) 5 litre containers.
- (ii) White high density polyethylene (HDPE) 500 ml bottles.
- (iii) White high density polyethylene (HDPE) 250 ml bottles.
- (iv) White high density polyethylene (HDPE) 125 ml bottles.

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

See section 4.4.

7 MARKETING AUTHORISATION HOLDER

Regent Medical Overseas Limited
Medlock Street
Oldham
Lancashire OL1 3HS
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA1218/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30 May 1980

Date of last renewal: 30 May 2010

10 DATE OF REVISION OF THE TEXT

November 2019