1. NAME OF THE MEDICINAL PRODUCT

Hibiwash

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Gluconate 4% w/v
(incorporated as Chlorhexidine Gluconate Solution)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Liquid

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

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 Hibiwash and wash for one minute cleaning the fingernails with a brush or scraper. Rinse, apply a further 5 ml of Hibiwash and continue washing for a further 2 minutes. Rinse thoroughly and dry.

Antiseptic handwash on the ward
Wet the hands and forearms, apply 5 ml of Hibiwash and wash for 1 minute. Rinse thoroughly and dry.

Pre-operative skin antisepsis for the patient
The patient washes his whole body in the bath or shower on at least 2 occasions, usually the day before and the day of operation as follows: The day before operation the patient washes with 25 ml of Hibiwash beginning with the face and working downwards paying particular attention to areas around the nose, axillae, umbilicus, groin and perineum. The body is then rinsed and the wash repeated with a further 25 ml, this time including the hair. Finally the patient rinses his entire body thoroughly and dries on a clean towel. This procedure should be repeated the following day. Patients confined to bed can be washed with Hibiwash using a standard bed-bath technique. Conventional disinfection of the operation site will then be performed when the patient is in theatre.

Post-operative skin antisepsis for the patients
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.

Children and elderly patients
There are no special dosage recommendations for either elderly patients or children. The normal adult dose is appropriate unless recommended by the physician.

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).

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4.4 Special warnings and precautions for use

Hibiwash 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. HibiWash 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).

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 HibiWash, care must be taken to ensure no excess product is present prior to application of the dressing.

Hibiwash is flammable. Do not use with electrocautery procedures or other ignition sources until dry.

Isopropyl alcohol may very rarely cause skin irritations such as erythema, dryness, contact allergies, burning sensation.

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

Do not inject or use in body cavities.

4.5 Interaction with other medicinal products and other forms of interaction

See section 6.2.

4.6 Fertility, pregnancy and lactation

There is no evidence of any adverse effects on the foetus arising from the use of Hibiwash as a handwash during pregnancy and lactation. 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

Very Common (≥ 1/10); Common (≥ 1/100, < 1/10); Uncommon (≥ 1/1,000, < 1/100); Rare (≥ 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:

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose
This has not been reported.

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
Pharmacotherapeutic group: antiseptics and disinfectants, ATC code: D08AC02

Mode of action – chlorhexidine has a wide range of antimicrobial activity. 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. 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.

5.2 Pharmacokinetic properties
Retention and uptake kinetics and factors influencing the pharmacokinetics.
Chlorhexidine appears to be very poorly absorbed. No blood levels were detected during a 3-week simulated clinical use of Hibiwash.

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
Cocamidopropylamine oxide
Glycerol
Macrogol-7 Glycerol Cocoate
Gluconolactone
Purified water
Sodium hydroxide (for pH-adjustment)

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

6.3 Shelf life
36 months.

6.4 Special precautions for storage

Do not store above 25 ºC.

6.5 Nature and contents of container
HDPE bottles containing 125 ml, 250 ml, 500 ml and 5 litres

6.6 Special precautions for disposal and other handling
See section 4.4.

7. MARKETING AUTHORISATION HOLDER
Regent Medical Ltd
Medlock Street
Oldham
Lancashire
OL1 3HS
United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)
PL 22099/0003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
25/10/2023

10. DATE OF REVISION OF THE TEXT
30/10/2023