SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Hibiwash 40 mg/ml cutaneous solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of cutaneous solution contains 40 mg chlorhexidine digluconate.
For a full list of excipients see Section 6.1

3. PHARMACEUTICAL FORM

Cutaneous solution

A clear, colourless to pale yellow viscous liquid.

4. CLINICAL DATA

4.1 Therapeutic indications

<invented name> is indicated in adults and children as an antiseptic for preoperative and post-operative disinfection of the hands and skin.

4.2 Posology and method of administration

Posology

Preoperative surgical hand disinfection

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

Antiseptic handwash on the ward

Wet the hands and forearms, apply 5 ml of <invented name> and wash for one minute. Rinse thoroughly and dry.

Pre-operative skin antisepsis for the patient

The patient washes his/her whole body in the bath or shower on at least two occasions, usually the day before and the day of operation as follows:

- The day before the operation: the patient washes with 25 ml of <invented name> beginning with the face and working downwards paying particular attention to areas around the nose, axillae, umbilicus, groin, perineum and buttocks. 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.
- The day of the operation: The procedure above is repeated.

Patients confined to bed can be washed with <invented name> using a standard bed-bath technique. Conventional disinfection of the operation site will then be performed when the patient is in theatre.

Pre-operative disinfection of the surgical area

Only remove hair from the surgical site if necessary.

Swab the skin with <invented name> for up to 2 mins, then swab the area with sterile water. Remove any foam and dry.

Post-operative skin antisepsis for the patient

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

Cleansing of the skin in conditions that are primarily bacterial or likely to be superinfected

Wet the affected area and apply 5 ml of <invented name> and wash for one minute. Rinse thoroughly and dry.

Paediatric and elderly populations

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

Use with care in premature infants or infants under two months of age: This product may cause irritation or chemical burns (see Sections 4.4 and 4.8).

Method of administration

For external use only.

4.3 Contraindications

Hypersensitivity to the active substance chlorhexidine digluconate or to any of the excipients listed in Section 6.1.

Keep out of the eyes and avoid contact with the brain, meninges and middle ear (see Section 4.4).

4.4 Special warnings and precautions for use

For external use only. This medicine should not be swallowed.

This medicine should not be applied on to the ears or inside the mouth or other mucosae.

<invented name> must not come into contact with the eye. Serious cases of persistent corneal injury, potentially requiring corneal transplant, were reported following accidental ocular exposure to chlorhexidine containing medicinal products despite taking eye protective measures due to migration of solution beyond the intended surgical preparation area. Extreme care must be taken during application to ensure that <invented name> does not migrate beyond its intended application site into the eyes. Particular care should be taken in anaesthetised patients, who are unable to immediately report ocular exposure.

In the event of accidental contact with eyes or ears wash out promptly and thoroughly with water. If contact with the eyes an ophthalmologist's advice should be sought.

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.

<invented name> should not be used in case of deep and extensive wounds. Although chlorhexidine absorption through the skin is minimal, the risk of systemic effects cannot be excluded. These effects may be boosted in case of repeated applications, large areas, occlusive dressing, or mucosae.

Do not inject or use in body cavities.

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 <invented name>, care must be taken to ensure no excess product is present prior to application of the dressing.

<invented name> is flammable. Do not use with electrocautery procedures or other ignition sources until dry.

Not to be used for disinfecting surgical materials.

Paediatric population

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.

4.5 Interactions with other medicines and other interactions

No interaction studies have been performed (see Section 6.2).

This medicine should not be used in combination or after application of other cationic compounds, anionic soaps and detergents, iodine, heavy metal salts and acids.

4.6 Fertility, pregnancy and lactation

There is no evidence of any adverse effects on the foetus arising from the use of <invented name> as a handwash or bodywash during pregnancy and lactation.

Pregnancy

No effects during pregnancy are anticipated, since systemic exposure to chlorhexidine is negligible.

<invented name> can be used during pregnancy.

Lactation

No effects on the breastfed newborn / infant are anticipated since the systemic exposure of the breast-feeding woman to chlorhexidine is negligible. Breast-feeding women should avoid using it on their breasts.

4.7 Effects on the ability to drive and use machines

<invented name> has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The following adverse events are described in the scientific literature.

The frequency categories for each adverse drug reaction include: 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); or not known (cannot be estimated from the available data).

System Organ Class (SOC)	**Frequency**	
	Very rare (<1/10,000)	**Not known (cannot be estimated from the available data)**
Immune system disorders:		Hypersensitivity including anaphylactic shock. Delayed hypersensitivity including allergic contact dermatitis
Eye disorders:		Corneal erosion, epithelium defect/corneal injury, significant permanent visual impairment*.
Injury, poisoning and procedural complications:		Chemical burns in neonates.
Skin and subcutaneous tissue disorders		Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticaria, skin irritation, and blisters.

Footnote: Cases of severe corneal erosion and permanent significant visual impairment due to inadvertent ocular exposure have been reported post-marketing, leading to some patients requiring corneal transplant (see Section 4.4).

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 the national reporting system listed in Appendix V.

4.9 Overdose

No cases of overdose have been reported with this product.

In case of accidental ingestion proceed with the gastric lavage and protect the gastrointestinal mucosa.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antiseptics and disinfectants. Biguanides and aminidines**,** ATC code: D08A C52

Mechanism of action

Chlorhexidine gluconate is a cationic biguanide used as a topical antiseptic. It has a broad spectrum of antimicrobial activity and is effective against a wide range of gram-negative and gram-positive vegetative bacteria, yeasts, dermatophyte fungi and lipophilic viruses.

The molecule is positively charged and reacts with the negatively charged microbial cell surface, thereby destroying the integrity of the cell membrane. Subsequently, the molecule penetrates the cell and causes leakage of intracellular components leading to cell death.

Chlorhexidine is inactive against bacterial spores except at elevated temperatures.

Pharmacodynamic effects

Because of its cationic nature, chlorhexidine binds strongly to skin, mucosae 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.

Paediatric population

Topical chlorhexidine is suitable for use in paediatric populations.

5.2 Pharmacokinetic properties

The absorption of chlorhexidine gluconate through the skin is minimal. Trace levels of chlorhexidine have been detected in blood samples from newborns following bathing in 4% chlorhexidine solution, however, there have been no reports of systemic adverse consequences arising from chlorhexidine absorption in paediatric patients.

5.3 Preclinical Safety data

Nonclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction.

6. PHARMACEUTICAL DATA

6.1 List of excipients

Poloxamer
Isopropyl alcohol

Cocamidopropylamine oxide
Glycerol (E422)

Macrogol-7-Glycerol-Cocoate

D-gluconolactone

Sodium hydroxide (for pH adjustment) (E524)
Purified water

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

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

HDPE bottles with a polypropylene screw cap, containing 125 ml, 250 ml, 500 ml and an HDPE bottle with an HDPE screw cap, containing 5 litres.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements for potentially flammable materials.

7. MARKETING AUTHORISATION HOLDER

<To be completed nationally>

8. MARKETING AUTHORISATION NUMBER(S)

<To be completed nationally>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<To be completed nationally>

10. DATE OF REVISION OF THE TEXT

2024-11-14