

HiBiScrub®

HiBiScrub® is an antimicrobial skin cleanser containing 4% w/v Chlorhexidine gluconate



Long-lasting sustained protection

Chlorhexidine gluconate, the active ingredient in HiBiScrub binds to the skin forming an effective barrier that will keep killing bacteria and protecting long after application, showing up to 6 hours residual effect¹ and increased efficacy upon repeated application.²

Effective kill rate on many HAI's in 1 minute

HiBiScrub has an impressive kill rate of within 1 minute for many organisms that are implicated with healthcare associated infections.³ The active, Chlorhexidine gluconate is also extremely effective against a wide range of Gram positive and Gram negative bacteria, yeast, fungi and viruses.⁴

Kind to skin

Containing a blend of emollients, dermatologically tested HiBiScrub helps soften and hydrate the skin. Proven to be significantly less irritating than a leading 4% Chlorhexidine gluconate solution, HiBiScrub also reduces moisture loss even with frequent use.^{5,6}

Short and effective contact times

Proven short contact times on listed test standards. HiBiScrub kills several Gram positive and Gram negative organisms that are resistant to some of the most widely used antibiotics in as little as 15 seconds.⁷

Effective kill rate on many HAI's in 1 minute

4% Chlorhexidine gluconate is more effective than PVPI or triclocarban medicated soap⁸ and can be used as part of a care bundle to help reduce surgical site infections. In a recent study, whole body washing with HiBiScrub in conjunction with a nasal antibiotic reduced the risk of hospital associated S aureus infections by nearly 60%.⁹

Description/Size	Product code
HiBiScrub 250 ml	10008781
HiBiScrub 500 ml	10008780
HiBiScrub 5 litres	10008779
Dispenser Pump 5 ml (for use with HiBiScrub 500 ml: 10008780)	10003652

Test standard	Micro organisms	Result
EN 1499	E coli	1 minute ¹⁰
Based on EN 1276	P aeruginosa P aeruginosa (multi-antibiotic resistant strain) A baumannii (multi-antibiotic resistant strain) E coli VRSA E faecalis ESBL producing E coli ESBL producing E cloacae ESBL producing E aerogenes ESBL producing K pneumoniae S aureus E faecium VISA	15 seconds ⁷ 30 seconds ⁷ 1 minute ⁷ 3 minutes ⁷
Based on prEN 12054	EMRSA 15 and 16	1 minute ¹¹
EN 1040	Staphylococcal aureus and Pseudomonas aeruginosa	1 minute ¹²
Based on prEN 12054	E hirae	1 minute ¹³
EN 1275	C albicans yeasticidal and fungicidal	5 minutes ¹⁴
DIS/TSS-7 (EPA method)	H5N1 Avian Flu (NIBRG-14 construct)	20 seconds ¹⁵
ASTM E1052-99	Influenza A H1N1(Swine Flu variant VR-333)	30 seconds ¹⁶

GSL Price:

HiBiScrub 250ml: £4.25, HiBiScrub 500ml: £5.25.

1. Name of Product

HiBiScrub

2. Composition

Chlorhexidine Gluconate 4.0% w/v (incorporated as Chlorhexidine Gluconate Solution Ph. Eur.)

3. Pharmaceutical Form

Liquid.

4. Clinical Particulars**4.1 Therapeutic indications**

HiBiScrub is an antimicrobial preparation for pre-operative surgical hand disinfection, antiseptic handwashing on the ward and pre-operative and post-operative skin antiseptics 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 HiBiScrub and wash for 1 minute cleaning the fingernails with a brush or scraper. Rinse, apply a further 5 ml of HiBiScrub 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 HiBiScrub and wash for 1 minute. Rinse thoroughly and dry.

Pre-operative skin antiseptics 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 HiBiScrub 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 HiBiScrub 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 antiseptics 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).

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).

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 HiBiScrub 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 ($\geq 1/10$); 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).

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**

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 HiBiScrub.

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**

D-glucono-delta-lactone
Isopropyl alcohol
Lauryl dimethyl amine oxide
Perfume (herbacol 015393 TD)
Polyoxyethylene-polyoxypropylene block copolymer
Ponceau 4R [E124]
Sodium hydroxide
Glycerol
Macrogol-7 Glycerol Cocoate
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

36 months.

6.4 Special Precautions for Storage

Do not store above 25°C.

6.5 Nature and contents of container

HDPE bottles containing 250 ml, 500 ml and 5 litres.

6.6 Special precautions for disposal and other handling

See section 4.4.

7. Manufacturing Authorisation Holder

Regent Medical Overseas Ltd, Two Omega Drive, Irlam, Manchester, M44 5BJ, United Kingdom.

8. Marketing Authorisation Number

PL 21855/0002.

9. Date of text

February 2013.

References: 1. JTanner et al. A fresh look at perioperative body washing. *Journal of Infection Prevention*. 2012; Vol 13: 11-15. 2. Faogali J et al. Comparison of the immediate, residual, and cumulative antibacterial effects of Novaderm R, Novascrub R, Betadine Surgical Scrub, Hibiclen, and liquid soap. 1995. 3. Mölnlycke Health Care Report REPR0495. 4. Denton, GW. Chlorhexidine. Chapter 15 in *Disinfection, Sterilization, and Preservation*. Ed. Block SS. Fifth Ed. Lippincott Williams and Wilkins. 2001. 5. Mölnlycke Healthcare Report REPR0781. 6. Larson EL et al. Antimicrob Agents Chemo. Efficacy of alcohol-based rinses under frequent use conditions. 1986; Vol 30, No. 4: 542-4. 7. Mölnlycke Healthcare Report REPR0432. 8. Garibaldi RA et al. *Journal of Hosp Infection*. Prevention of intraoperative wound contamination with chlorhexidine shower and scrub. 1988; Vol 11; 5-9. 9. Bode LGM et al. *NEJM*. Preventing Surgical-Site infections in nasal carriers of *Staphylococcus aureus*. 2010; Vol 362; 9-17. 10. Mölnlycke Healthcare Report REPR0591. 11. Mölnlycke Healthcare Report REPR0145. 12. Mölnlycke Healthcare Report REPR0871. 13. Mölnlycke Healthcare Report REPR0295. 14. Mölnlycke Healthcare Report REPR0537. 15. Mölnlycke Healthcare Report REPR0150. 16. Mölnlycke Healthcare Report REPR0597.

Find out more at www.molnlycke.co.uk

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