



Hibiwash®
bonded to skin



HIBIWASH® CHLORHEXIDINE GLUCONATE

Hibiwash® is an antimicrobial full-body wash that **bonds to and cares for skin, whilst killing microorganisms.**

It is your **trusted partner** in helping prevent infections, promote skin's integrity and save time before performing surgical procedures.

With 4% Chlorhexidine Gluconate


Mölnlycke®

SURGICAL SITE INFECTIONS

AN ONGOING PROBLEM

Managing surgical site infections (SSIs) and hospital acquired infections (HAIs) is a real and growing problem, with serious implications.

An SSI is an infection that occurs after an invasive operation in the location where the surgery took place. It is the second most common type of HAI in the EU.¹ Studies have shown that the patient's skin is responsible for most of the pathogens that cause SSIs.² Up to 33 % of the population naturally carry Staphylococcus aureus on their skin. Staphylococcus aureus can also be found on the surgeons' hands.³



11.8% avg. of surgeries in low and middle income countries will result in a SSI⁴



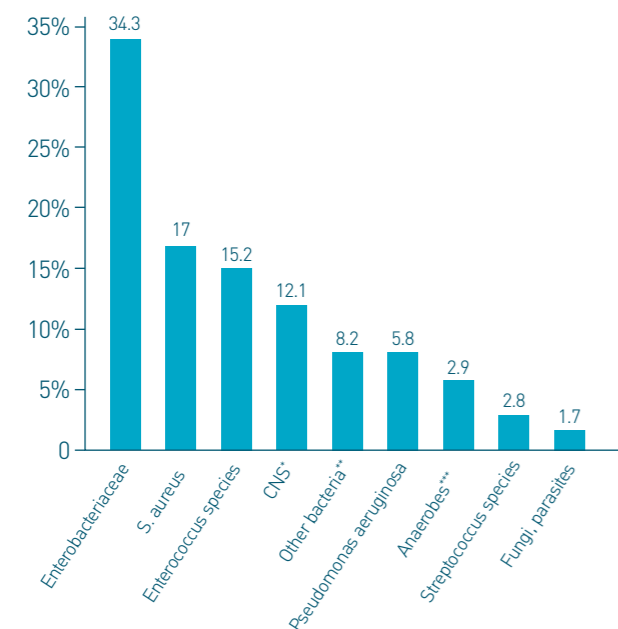
7% of patients in high income countries will have HAI⁵



10% of lower income countries will have a HAI⁵

PROPORTION OF SSI WITH ORGANISM DATA (%)

Inpatient and readmission cases (n=9,858)⁶



SURGICAL SITE INFECTIONS...

...RESULT IN AN ESTIMATED

19.1 BILLION EUROS⁴

IN ADDITIONAL COSTS

...INCREASE THE LENGTH OF STAY BY

6.5 DAYS IN THE EU⁴

...HAVE A

NEGATIVE IMPACT

ON PATIENT QUALITY OF LIFE AND ON GLOBAL HEALTHCARE SYSTEMS

...TRIGGER FURTHER DEPENDENCE OF

ANTIBIOTICS,
POTENTIALLY LEADING TO AN INCREASE IN ANTIBIOTIC RESISTANCE

* Hibiwash[®] is not proven to be effective against *S. haemolyticus*.

** Mostly comprising unspecified diphtheroids, "other" gram-positive organisms and bacilli. Hibiwash[®] is not proven to be effective against *Stenotrophomonas maltophilia*.

*** Hibiwash[®] is not proven to be effective against *C. diff* spores.

A RISK TO ELIMINATE

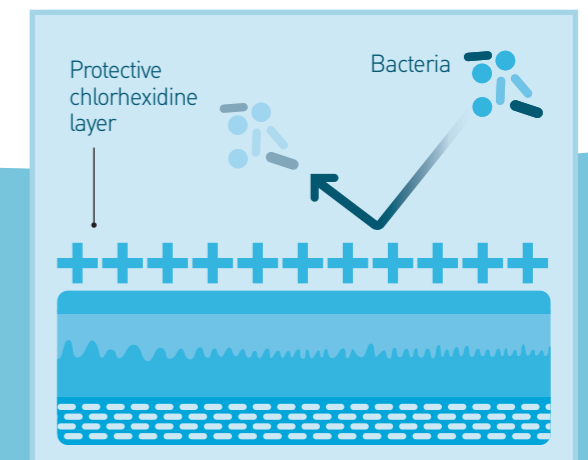
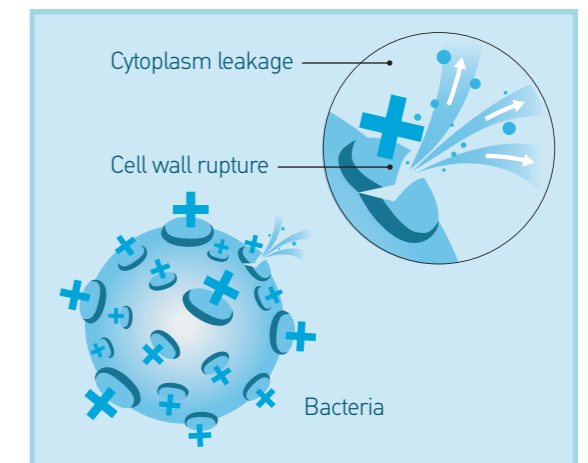
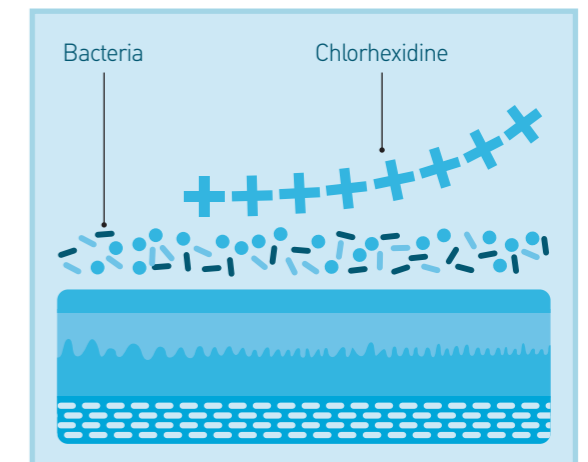
With the increased focus on infection prevention globally, now is more important than ever to minimise the risks of healthcare associated infections, such as SSIs.

DID YOU KNOW:

...that Hibiwash[®] can be used for effective prevention against the **most common causes of SSIs?**

CHLORHEXIDINE GLUCONATE – HOW DOES IT WORK?

CHG binds to the cell wall of the bacteria causing it to rupture, leading to cell death. CHG molecules bind to the proteins in human tissues and provide a layer of prolonged protection.⁷





HIBIWASH®

AN EFFECTIVE ANTIMICROBIAL SKIN CLEANSER PROTECTING THE PATIENT IN THE HOSPITAL AND AT HOME



Ideal for whole body washing for preadmission patients

- Post-operative infections reduced to 8% from 17.5% in a study of 341 patients using Chlorhexidine whole body washing.⁸
- 20-fold reduction in skin bacteria count after showering three times with 4% Chlorhexidine in a randomised controlled trial.⁹
- Hibiwash® reduces skin flora by 94% with the first whole body wash and then by a further 77% with the second.¹⁰



Fast acting with a long lasting effect

Hibiwash® is not absorbed into the skin but binds to it, forming a protective layer even after the rinse off that efficiently kills microorganisms, for hours after application.¹⁴ Furthermore, unlike povidone iodine, Hibiwash® is not inactivated by bodily fluids.¹⁶



Effective in a wide range of microorganisms

Hibiwash® is effective against a wide range of microbes including Gram positive and Gram negative bacteria, yeast, fungi and viruses, and reduces bacterial load more efficiently than povidone iodine.^{11,12} In combination with a nasal antibiotic Hibiwash® was shown to significantly decrease the risk for hospital associated *S. aureus* infections by up to 60%.¹³



Tough against microbes and gentle to the skin^{17,18}

Hibiwash® is dermatologically tested, it has no colour, no fragrance, no traces of soya oil and contains emollients. It has been shown to be gentle on the skin even when used frequently. This is beneficial since repeated application of Hibiwash® has been shown to increase the antimicrobial efficacy.¹⁹

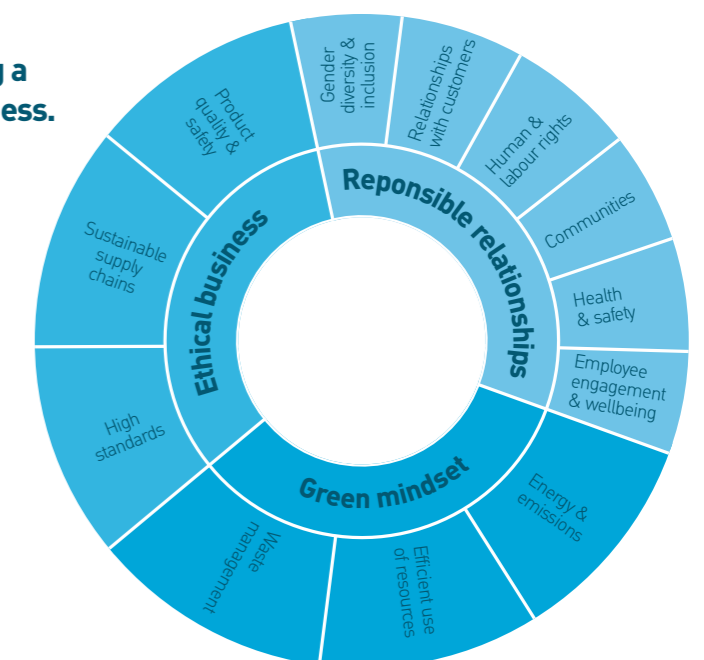
Efficacy information

PhEur 5.1.11 - bactericidal and yeasticidal

Please speak to your Mölnlycke contact person for information on product codes, on packaging and product accessories in your local market.

At Mölnlycke, we are committed to becoming a more sustainable business.

Hibiwash® is part of our sustainability development. Our primary packaging (bottles) and transport shippers (cardboard) are all made of recyclable material.

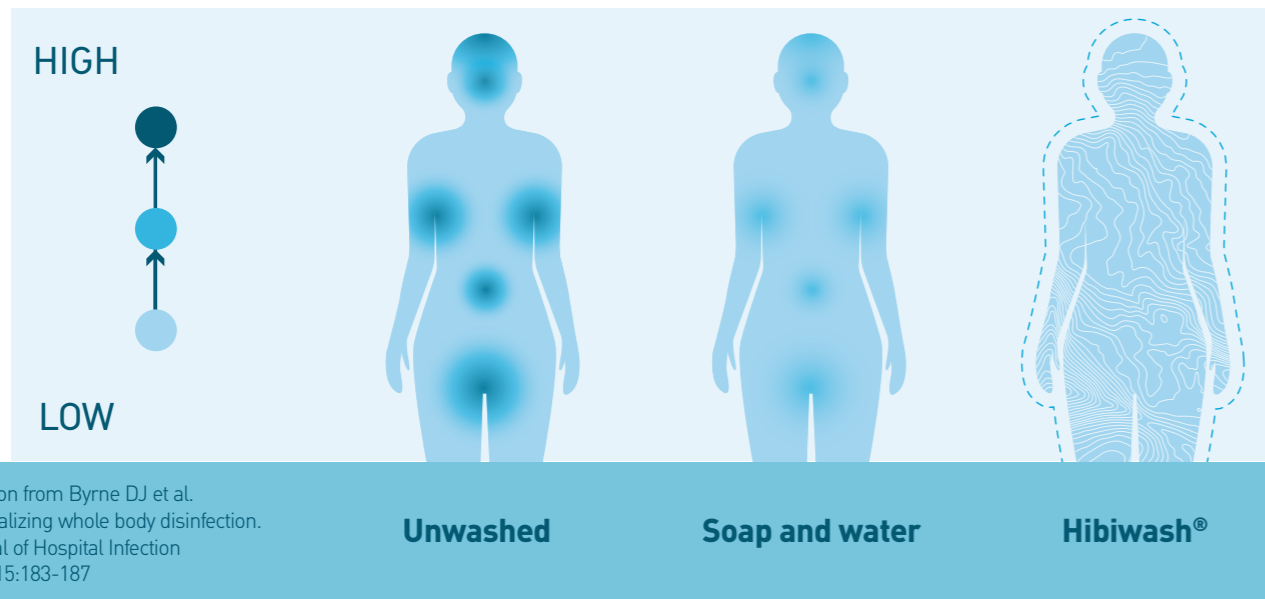


PROTECTING YOUR PATIENTS

SKIN – THE SOURCE OF THE PROBLEM

Studies have shown that the patient's skin is responsible for most of the pathogens that cause SSIs⁵. Up to 33% of the population naturally carry Staphylococcus aureus on their skin.^{2,3}

MICROORGANISMS RESIDUE LEVELS AFTER WASHING



Hibi products have been used in hospitals for many decades

WHAT IF THERE WAS AN EASY WAY TO ENSURE A CLEAN SURGERY?

There is! It's Hibiwash®

With easy to follow instruction Hibiwash® can be used for pre-operative and post-operative whole body washing to reduce the chance of SSIs.

- Kills a vast number of microorganisms¹¹
- Provides hours of protection¹⁵
- Gentle to skin¹⁸



Help us to reduce the **11 in 100 chance** of a surgical site infection.²⁰

Together let's move towards zero.

FIND OUT MORE AT WWW.MOLNLYCKE.CO.UK

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Mediwash 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

4.2 Posology and method of administration

Posology

Preoperative 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 two minutes. Rinse thoroughly and dry.

Antiseptic handwash on the ward

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

Pre-operative skin antiseptics 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 Hibiwash® 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 Hibiwash® 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 Hibiwash® for up to 2 mins, then swab the area with sterile water. Remove any foam and dry.

Post-operative skin antiseptics 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 Hibiwash® 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. 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 eyes, ears or inside the mouth or other mucosae.

In the event of accidental contact with eyes or ears it is recommended to wash out promptly and thoroughly with water. 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.

Hibiwash® 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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: antiseptics and disinfectants. Biguanides and amidines, ATC code: D08A C02

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. 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

The use of chlorhexidine solutions, both alcohol-based and aqueous, for skin antiseptics 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 Hibiwash® as a handwash or bodywash during pregnancy and lactation.

Pregnancy

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

Hibiwash® 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).

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.

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
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.

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.

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6. PHARMACEUTICAL DATA

6.1 List of excipients

Poloxamer Isopropyl alcohol
Cocamidopropylamine oxide Glycerol [E422]
Macrogol-7-Glycerol-Cocaoate 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.

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

Mölnlycke Health Care Ltd, Unity House, Medlock Street, Oldham, OL1 3HS UK. Tel: 0800 731 1876 Email: ors.uk@molnlycke.com

8. MARKETING AUTHORISATION NUMBER(S)

HQIM005143UK

9. DATE OF FIRST AUTHORISATION/RENEWAL

OF THE AUTHORISATION 23/10/2023

10. DATE OF REVISION OF THE TEXT

23/10/2023

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