

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

2% Chlorhexidine Gluconate Cloth

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine gluconate 2% w/v = 20 mg/ml solution (equivalent to 500 mg chlorhexidine gluconate per cloth).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Impregnated cloth.

White cloth.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

- Helps reduce bacteria that can potentially cause skin infection
- For preparation of skin prior to surgery
- Provides rapid bactericidal action against a broad spectrum of microorganisms
- Significantly reduces the number of microorganisms on intact skin
- Demonstrates continued antimicrobial activity for up to 6 hours after application

4.2 Posology and method of administration

Cutaneous use only.

Use only on intact skin.

To open, tear seal where indicated (2-pack) or peel open the resealable package (6-pack). Remove cloths from package. Avoid contact between cloths and outside of package to reduce risk of contamination.

For use as part of an advance preoperative cleansing regimen: Regimen should be performed the night before and the morning of a surgical procedure. Use one cloth to prepare each desired area of the body by washing skin, completely wetting treatment area.

2-pack: Use one cloth to prepare each desired area of the body by washing skin, completely wetting treatment area.

6-pack: Use one cloth to prepare each area of the body by washing skin, completely wetting treatment area as follows:

- Wipe the neck, chest and stomach;
- Wipe both arms, starting each with the shoulder and ending at the fingertips paying particular attention to the axillary area;
- Wipe the right and left hips followed by the groin paying particular attention to the skin folds in the abdominal and groin areas;
- Wipe both legs, starting at the thigh and ending at the toes;
- Wipe the back, starting at the base of the neck and ending at the waistline;
- Wipe the buttocks.

Do not rinse or apply any lotions, moisturizers or cosmetics after prepping.

For General Skin Antisepsis and cleansing:

Use one cloth for each area of the body where skin antisepsis is desired. Do not use on open skin wounds or broken skin.

General information:

Discard each cloth after a single use. After package has been opened, discard any unused cloths.

4.3 Contraindications

Hypersensitivity to chlorhexidine gluconate or to any of the excipients (see sections 4.4 and 4.8).

Do not use on premature or low birthweight infants (see section 4.4).

Do not use on infants less than 2 months of age or receiving phototherapy.

Do not use immediately prior to invasive techniques, such as venepuncture, lumbar puncture or surgery.

Do not use on open skin wounds or broken skin.

4.4 Special warnings and precautions for use

Product and packaging are not sterile.

Keep out of eyes, ears and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with water immediately.

2% Chlorhexidine Gluconate Cloth contain 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 it is likely to be very rare.

2% Chlorhexidine Gluconate Cloth 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 2% Chlorhexidine Gluconate Cloth, care must be taken to ensure no excess product is present prior to application of the dressing

Keep out of the reach and sight of children.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Pregnancy and breast-feeding

No effects during pregnancy are anticipated, since systemic exposure to chlorhexidine is negligible taking into consideration the low systemic exposure following topical use of the chlorhexidine impregnated cloths.

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to chlorhexidine is negligible.

However 2% Chlorhexidine Gluconate Cloth should not be used at the breast to avoid any uptake by the newborn during breast feeding.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Skin and subcutaneous tissue disorders:

Common ($\geq 1/100$ to $< 1/10$): Skin irritation

Frequency unknown: Chemical burns in neonates, allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticaria, skin irritation, and blisters

Immune system disorders:

Very rare ($< 1/10,000$): Generalised allergic reactions.

Frequency unknown: Hypersensitivity including anaphylactic shock (see sections 4.3 and 4.4).

When using the 2% Chlorhexidine Gluconate Cloth, the skin should be completely dry and cool. Showering or shaving immediately before using 2% Chlorhexidine Gluconate Cloth may increase skin irritation. Shaving should be suspended at least 2 days prior to surgery on all areas of the body, including the face, legs, underarms, etc. If skin irritation persists, rinse the affected areas and discontinue use.

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.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form <http://sideeffects.health.gov.il>

4.9 Overdose

Overdosage is unlikely because of the low dermal absorption. Ingestion is highly unlikely.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiseptics and disinfectants, ATC code: D08AC02

Chlorhexidine is a disinfectant which is effective against a wide range of vegetative Gram-positive and Gram-negative bacteria. The wide range of microorganisms against which chlorhexidine is active makes it suitable for broad spectrum disinfection of skin prior to surgery to reduce risk of infection. Effective against MRSA, VRE, *Acinetobacter baumannii*, *Pseudomonas aeruginosa* and various *Streptococcus* species.

The effect against some gram-negative bacteria (*Pseudomonas*- and *Proteus*-types) and against certain yeasts, dermatophytes and mycobacteria is poor. It is ineffective

against bacteria spores and fungus spores, viruses and putrefactive fungi.

Chlorhexidine gluconate is effective against enveloped viruses (e.g. herpes simplex virus, HIV, cytomegalovirus, influenza, and RSV) but it is substantially less active against non-enveloped viruses (e.g., rotavirus, adenovirus, and enteroviruses).

Chlorhexidine significantly reduces the number of microorganisms on intact skin and demonstrates continued antimicrobial activity for up to 6 hours after application.

Chlorhexidine is inactive against bacterial spores.

5.2 Pharmacokinetic properties

No formal pharmacokinetic studies have been performed with chlorhexidine gluconate solution in an impregnated cloth. Chlorhexidine binds strongly to skin and is very poorly absorbed. Percutaneous absorption is minimal.

5.3 Preclinical safety data

Chlorhexidine is a well established active ingredient and relevant information is provided in other sections of the leaflet.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

purified water, propylene glycol, glycerin, aloe vera, glucono delta lactone, dimethicone 350 cst, polysorbate 20, Igepal CO 630, Shaw Mudge fragrance.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the printing materials.

6.4 Special precautions for storage

Store below 25°C. Avoid heat above 40°C. Store flat.

6.5 Nature and contents of container

Flexible film, heat-sealed packages contain either 2, 3x2 or 6 impregnated polyester cloths.

The 2-pack product consists of a stack of 2 polyester cloths impregnated with chlorhexidine, a polyethylene foam carrier and film overwrap with polyethylene inner layer.

The 6-pack product consists of a stack of 6 cloths impregnated with chlorhexidine, wrapped in a polyethylene foam carrier and film overwrap with polyethylene inner layer.

Cartons containing 48 or 96 packages each comprising of 2 impregnated cloths (2 Cloths x 1 package).

Cartons containing 32 packages each comprising of 6 impregnated cloths (2 Cloths x 1 package, 3 pack in clear overwrap)

Cartons containing 32 packages each comprising of 6 impregnated cloths (6 Cloths x 1 package).

6.6 Special precautions for disposal

Dispose of as solid waste. Do not flush cloths in toilet.

7 MARKETING AUTHORISATION HOLDER

Bio-Med Pharma Ltd.
1 Hazerem Street
Kadima 6092000

8 MANUFACTURER

Sage Products LLC.
3909 Three Oaks Road, Cary, IL 6001 USA

9 MARKETING AUTHORISATION NUMBER

170-99-36427-00

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