AUSTRALIAN PRODUCT INFORMATION – SOLUPREP® ANTISEPTIC WIPES, SWABS, SPONGES, SOLUTION

1 NAME OF THE MEDICINE

Chlorhexidine gluconate and isopropyl alcohol

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Solution, Sponges, Swabs, Wipes all contain: Chlorhexidine gluconate 2%w/v and Isopropyl alcohol 70%v/v

For full list of excipients, see Section 6.1 List of excipients

3 PHARMACEUTICAL FORM

Solution (clear, tinted red);
Sponges (clear, tinted red);
Swabs (clear, tinted red);
Wipes (clear);
Cutaneous solution

Not all solutions may be marketed.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Antiseptic for preparation of the patient's skin prior to invasive procedure on dry skin sites only. Helps reduce bacteria that potentially can cause skin infection.

4.2 DOSE AND METHOD OF ADMINISTRATION

For cutaneous use.

Not recommended for use on infants less than 2 months of age.

The choice of application, (sponge, wipe, swab or solution), will depend on the procedure being undertaken, the coverage area required and the clinician's preference.

Application type	Coverage area	Product volume
Sponge (2s)	40cm x 40cm (per sponge)	50mL
Sponge (4s)	40cm x 40cm (per sponge)	97mL
Wipe (small)	6cm x 7cm	0.65mL
Wipe (large)	10cm x 10cm	1.5mL
Swab (small)	10cm x 11cm	1.6mL
Swab (large)	20cm x 20cm	5.2mL
Solution (225mL)	88cm x 87cm (per 100mL)	225mL
Solution (500mL)	88cm x 87 (per 100mL)	500mL

Refer to specific application type below for directions for use and dry times.

Sponges:

100.25 (4 pack) – Each tray contains 4 sponges and 97mL of tinted solution per tray; Maximum treatment area 40cm x 40cm per sponge

100.26 (4 pack) – Each tray contains 4 sponges and 97mL of clear solution per tray; Maximum treatment area 40cm x 40cm per sponge

100.27 (2 pack) – Each tray contains 2 sponges and 50mL of tinted solution per tray; Maximum treatment area 40cm x 40cm per sponge

Directions: For use on intact skin. Clean the area prior to application. Gently squeeze the package to allow equal distribution of the antiseptic. Peel apart the package and fold upper foil lid under the package to expose sponges. Using a sterile forcep, select one sponge half way down, ensure that half of the sponge extends past the forcep tip. Dab the sponge on others within the package to remove excess solution. Apply solution to the procedure site; use repeated back-and-forth strokes for at least 30 seconds. Completely wet treatment area. Select another sponge as necessary. Allow the solution to completely air dry (minimum of 3 minutes on hairless skin). Product is flammable until completely dry (see Section 4.4 Special Warnings and Precautions for Use). Do not allow solution to drip or pool. Do not blot or wipe procedure site after application. For single use. Discard after use.

Wipes:

101.06 Small – Each small wipe is a single unit dose and contains 0.65mL of clear solution; Maximum treatment area 6cm x 7cm

101.07 Large – Each large wipe is a single unit dose and contains either 1.5mL of clear solution; Maximum treatment area 10cm x 10cm

101.14 Large – Each large wipe is a single unit dose and contains 1.6mL of clear solution; Maximum treatment area 10cm x 10cm

Directions: For use on intact skin. Clean the area prior to application. Tear open packet and remove wipe. Do not unfold the wipe. Apply solution to the procedure site; use repeated back-and-forth strokes for at least 30 seconds. Allow the solution to completely air dry. Product is flammable until completely dry (see Section 4.4 Special Warnings and Precautions for Use). Do not blot or wipe procedure site after application. For single use. Discard after use.

Swabs:

102.03 Small – Each small swab is a single unit dose and contains 1.6mL of solution clear; Maximum treatment area 10cm x 11cm

102.08 Large – Each large swab is a single unit dose and contains 5.2mL of clear solution; Maximum treatment area 20cm x 20cm

102.09 Large – Each large swab is a single unit dose and contains 5.2mL of tinted solution; Maximum treatment area 20cm x 20cm

Directions: For use on intact skin. Clean the area prior to application. Peel apart the pouch and remove the applicator stick. Do not touch the foam tip. Apply solution to the procedure site; use repeated back-and-forth strokes for at least 30 seconds. Allow the solution to completely air dry. Product is flammable until completely dry (see Section 4.4 Special Warnings and Precautions for Use). Do not blot or wipe procedure site after application. For single use. Discard after use.

Solution:

103.15 (500mL bottle) - Each bottle contains 500mL of clear solution; Maximum treatment area 88cm x 87cm per 100mL
103.25 (500mL bottle) – Each bottle contains 500mL of tinted solution; Maximum treatment area 88cm x 87cm per 100mL
103.26 (225mL bottle) – Each bottle contains 225mL of tinted solution; Maximum treatment area 88cm x 87cm per 100mL
Directions: For use on intact skin. Clean the area prior to application. Pour the solution in a sterile bowl. Using an applicator, dip the applicator in solution and allow time for complete soak. Apply solution to the procedure site; use repeated back-and-forth strokes for at least 30 seconds. Allow the solution to completely air dry. Product is flammable until completely dry (see Section 4.4 Special Warnings and Precautions for Use). Do not blot or wipe procedure site after application. For single use. Discard after use.
Not all pack sizes may be marketed.

4.3 CONTRAINDICATIONS

Known hypersensitivity to chlorhexidine, isopropyl alcohol or any other ingredients listed in section 6.1, 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

For external use only on intact skin.

Not recommended for use on infants less than 2 months of age.

This product is non sterile, therefore should not be introduced to a sterile field without appropriate precautions.

The solution is flammable. Do not use electrocautery procedures or other ignition sources until the skin is completely dry. Tuck towels as needed under the area to be prepped to absorb excess solution. Remove any soaked material, 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 SoluPrep, care must be taken to ensure no excess product is present prior to application of the dressing.

To reduce risk of fire, apply solution carefully:

- Avoid getting solution into hair. Wet hair is flammable. Hair may take up to 1 hour to dry.
- Begin draping and/or using electrocautery only after solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair) and all wet materials are removed.

SoluPrep contains chlorhexidine. Rare but serious allergic reactions have been reported with products containing chlorhexidine. SoluPrep should not be administered to anyone with a potential history of an allergic reaction to a chlorhexidine-containing compound (see Section 4.3 and 4.8). Discontinue use if irritation and redness develop.

The solution is an irritant to eyes and mucous membranes. It should therefore be kept away from these areas. If contact occurs, rinse immediately and thoroughly with water.

Do not use for lumbar puncture or in contact with the meninges. In addition, direct contact with neural tissue or the middle ear must be avoided.

Caution should be exercised when using the product on children's skin.

Do not use on open skin wounds, broken or damaged skin.

Prolonged skin contact with alcohol containing solutions should be avoided. At the first sign of local skin reaction, the use of SoluPrep should be discontinued.

It is important to ensure that the correct method of application is followed (see Section 4.2). All SoluPrep products are for single use only. Discard after use.

Use in the elderly
No data available.

Paediatric use
No data available.

Effects on laboratory tests
No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

The product is applied topically and the expected systemic absorption is very low. No studies were performed to investigate its pharmacologic effects when used concomitantly with other medications.

4.6 FERTILITY, PREGNANCY AND LACTATION

There are no studies with this product in pregnant or lactating women.

Effects on fertility
The effects of chlorhexidine gluconate on human reproduction have not been studied.
No effects on fertility are anticipated since systemic exposure is negligible.

Use in pregnancy
No effects during pregnancy are anticipated since systemic exposure is negligible. SoluPrep may be used during pregnancy.

Use in lactation
No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman is negligible. SoluPrep may be used during breast-feeding.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

SoluPrep has no influence on the ability to drive or use machines.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Skin disorders:
Very rarely (<1/10,000) allergic or irritation skin reactions have been reported with chlorhexidine and isopropyl alcohol including: erythema, rash (e.g. erythematous, papular, or maculopapular), pruritus and blisters or application site vesicles. Other local symptoms have included skin burning sensation, pain and inflammation.
Frequency unknown: dermatitis, eczema, urticaria, chemical burns in neonates.

Immune disorders:
Frequency unknown: 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 that this is likely to be rare in the perioperative setting (see Section 4.3 and 4.4).
Common: application site rash, application site erythema, application site vesicles, application site pain and application site pruritus.
Frequency, type and severity of adverse reactions in children are expected to be the same in adults.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration 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 at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

There are no reports of overdose with this product.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Chlorhexidine, combinations, ATC code: D08A C52

Mechanism of action

Bisbiguanide antiseptics exert their lethal effect upon bacterial cells through non-specific interaction with acidic phospholipids of the cell membranes.

Chlorhexidine gluconate is a cationic biguanide. Its antimicrobial action is due to the disruption of the cell membrane and the precipitation of cell contents. It has a bactericidal or bacteriostatic action against a wide range of gram-positive and gram-negative bacteria. It is relatively ineffective against mycobacteria. It inhibits some viruses and is active against some fungi. It is inactive against bacterial spores. Chlorhexidine gluconate has a strong binding property to skin and has a residual property on the skin. Chlorhexidine gluconate is not neutralised in the presence of organic matter.

Isopropyl alcohol is a rapidly bactericidal and a fast-acting broad spectrum antiseptic, but is not considered persistent. Its mechanism of action appears to be denaturation of proteins.

SoluPrep is an antiseptic solution containing a combination of 2% Chlorhexidine gluconate in 70% Isopropyl alcohol, which is effective for both rapid and persistent reduction of bacterial load across various body regions for a broad spectrum of organisms. Isopropyl alcohol (70%) provides an immediate kill of transient and resident microorganisms on the stratum corneum and 2% Chlorhexidine gluconate binds to the superficial cell layers of the epidermis and provides a residual, or persistent, antimicrobial property that prevents regrowth of microorganisms.

Clinical studies with 2% Chlorhexidine gluconate in 70% Isopropyl alcohol have demonstrated that the combination offers equal or similar effectiveness in reducing skin bacterial load and more sustained antibacterial effects over longer periods after application, compared to the individual components alone, as well as to other commonly used antiseptics such as Povidone-iodine.

SoluPrep meets the following *in-vitro* test requirements established by the European Standards:

EN13727 – bactericidal activity
EN13624 – fungicidal and yeasticidal activity

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

There is little absorption of isopropyl alcohol or of chlorhexidine gluconate through intact skin. Pharmacokinetic studies have not been conducted with the product.

5.3 PRECLINICAL SAFETY DATA

Chlorhexidine gluconate and Isopropyl alcohol both have long histories of safe and effective use as patient preoperative skin preparation active ingredients and a large literature database on the safety and efficacy of these two active ingredients exists.

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Colourless solutions also contain purified water.

Tinted solutions also contain acid red 33, allura red AC and brilliant blue FCF as colouring agents in addition to purified water.

6.2 INCOMPATIBILITIES

Chlorhexidine is incompatible with soap and other anionic agents.

6.3 SHELF LIFE

3 years

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C. Do not refrigerate.
Flammable. Keep aware from fire or naked flame during use, storage and disposal.
Store in original package.

6.5 NATURE AND CONTENTS OF CONTAINER

Sponges:
100.25 (30 blister packs) each containing a white plastic tray comprising 4 sponges embedded with 97mL of tinted solution and sealed with a foil lid;
100.26 (30 blister packs) – each containing a white plastic tray comprising 4 sponges embedded with 97mL of clear solution and sealed with a foil lid;
100.27 (30 blister packs) – each containing a white plastic tray comprising 2 sponges embedded with 50mL of tinted solution and sealed with a foil lid;

Wipes:
101.06 Small (200 sachets) – each small wipe is a single unit dose embedded with 0.65mL of clear solution, sealed in an aluminium laminated with LDPE paper sachet;
101.07 Large (100 sachets) – each large wipe is a single unit dose embedded with 1.5mL of clear solution, sealed in an aluminium laminated with LDPE paper sachet;
101.14 Large (1000 sachets) – each large wipe is a single unit dose embedded with 1.6mL of clear solution, sealed in an aluminium laminated with LDPE paper sachet;

Swabs:
102.03 Small (50 sachets) – Each small swab (foam square attached to a handle) is a single unit dose and contains 1.6mL of clear solution, sealed in an aluminium plastic laminate sachet;
102.08 Large (30 sachets) - Each large swab (foam square attached to a handle) is a single unit dose and contains 5.2mL of clear solution, sealed in an aluminium plastic laminate sachet;
102.09 Large – (30 sachets) - Each large swab (foam square attached to a handle) is a single unit dose and contains 5.2mL of tinted solution, sealed in an aluminium plastic laminate sachet;

Solution:
103.15 (500mL HDPE bottle) – Each bottle containing clear solution
103.25 (500mL HDPE bottle) – Each bottle containing tinted clear red solution
103.26 (225mL HDPE bottle) – Each bottle containing tinted clear red solution

Not all pack sizes may be marketed.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

These products are for single use only.
In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

Chlorhexidine gluconate:

C28H42Cl2N10O7
Molecular weight 701.6g/mol
CAS number: 18472-51-0

Isopropyl alcohol:
CH3CHOHCH3
Molecular weight 60.1g/mol
CAS number: 67-63-0

7 MEDICINE SCHEDULE (POISONS STANDARD)

Not scheduled.

8 SPONSOR

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9 DATE OF FIRST APPROVAL

11 August 2014

10 DATE OF REVISION

6 March 2020