

SINGLE USE PRE-OPERATIVESKIN DISINFECTION

Prevase[®]

Chlorhexidine Gluconate 0.5% w/v in 70% v/v DEB Cutaneous Solution

SINGLE USE PRE-OPERATIVE SKIN DISINFECTION PRIOR TO SURGICAL PROCEDURES

Chlorhexidine gluconate based formula with long lasting residual effect1

- Flexible application to provide complete skin coverage for surgery
- Alcohol-based chlorhexidine solution to combine rapid efficacy with a persistent and cumulative barrier¹
- Single use medicinal product





Prevase®

Single use pre-operative skin disinfection prior to surgical procedures

SINGLE USE MEDICINAL PRODUCT

Prevase is supplied in a single use bottle and is applied with sterile holders and gauze. The flexible method of application allows complete coverage of the surgical site.

RESIDUAL PROTECTION AND BROAD SPECTRUM EFFICACY

Prevase contains the active ingredient chlorhexidine gluconate, which provides a persistent and cumulative effective barrier for at least 6 hours¹. In combination, chlorhexidine gluconate and 70% denatured ethanol (DEB) are fast acting and effective against a wide range of both gram positive and gram negative bacteria, yeast, fungi and viruses².

RECOMMENDED BY NICE GUIDANCE NG125

NICE recommends an alcohol-based solution of chlorhexidine as first choice for antiseptic skin preparation, unless contraindicated or the surgical site is next to a mucous membrane³.

PACKAGING AND ORDERING INFORMATION

PRODUCT	PACKAGING UNIT	ORDER CODE
Prevase®	24 x 200ml	3104520

SUMMARY OF PRODUCT CHARACTERISTICS

Name of Medicinal Product: Prevase Chlorhexidine Gluconate 0.5% w/v in 70% v/v DEB Cutaneous Solution. Active ingredient: Chlorhexidine Gluconate Solution 20% BP (Ph Eur) 2.5% v/v. Indications: For pre-operative skin disinfection prior to surgical procedures. Undesirable effects: Immune disorders Frequency not known: - Hypersensitivity including anaphylactic shock. Skin disorders Frequency not known: - Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticarial, skin irritation, and blisters. - Chemical burns in neonates and infants. Contraindications: Do not use in patients with a known hypersensitivity to the product or any of its components, especially in those with a history of possible chlorhexidine-related allergic reactions. Do not use in contact with eyes. brain, meninges, middle ear or external ear with a perforated tympanic membrane. Do not inject. When use is to be followed by diathermy do not allow pooling of the fluid to occur and ensure that the skin and surrounding drapes are dry. Do not use in body cavities. 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 Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard Warnings: Prevase 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. Prevase should not be administered to anyone with a potential history of an allergic reaction to a chlorhexidine-containing compound. Accidental ingestion: chlorhexidine is poorly absorbed orally. Treat with gastric lavage using milk, egg white, gelatine or mild soap. Employ supportive measures as appropriate. Accidental intravenous infusion - blood transfusion may be necessary to counteract haemolysis. 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, the 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 of sheets or other material in direct contact with the patient. Where occlusive dressings are to be applied to areas previously exposed to Prevase, care must be taken to ensure no excess product is present prior to application of the dressing. Fertility, pregnancy and lactation: None stated. Posology and method of administration: This product is applied topically. For single use only. Marketing authorisation holder: Ecolab Ltd, Unit 1 Wernddu Court, Caerphilly, CF83 3SG, United Kingdom. License Number: PL 04509/0062. Sales Status: GSL. Please read carefully the instructions on the SPC and on the label/leaflet. Date of revision of the text: November 2023.

INSTRUCTIONS FOR USE

This product is applied topically. For single use only.

Use with sterile gauze or cotton wool saturated with the solution. Allow any excess solution to drain off before applying to the skin. Use gentle strokes to prepare the site for 30 seconds, remove any excess liquid and allow to dry naturally for approximately 2 minutes to ensure adequate microbial reduction⁴.

When use is to be followed by diathermy do not allow pooling of the fluid to occur and ensure that the skin and surrounding drapes are dry.

Please refer to the Product Information Leaflet and the Summary of Product Characteristics

INGREDIENTS

Chlorhexidine Gluconate 0.5% w/v in 70% v/v DEB Cutaneous Solution

- Chlorhexidine Gluconate Solution 20% BP (Ph Eur) 2.5% v/v
- Denatured Ethanol B 96%
- Purified Water
- Carmoisine (E122)

TRAINING AND SUPPORT

Ecolab's national team of Clinical Implementation Specialists are available to support with all training and educational needs. Please contact your local Ecolab representative for further information.

REFERENCES

- ¹ Larson E (1995) APIC Guidelines
- ² Denton, GW;2001. Chlorhexidine. 15 in Disinfection, Sterilization and preservation. Ed. Block SS. Fifth Ed. Lippincott Williams and Wilkins.
- NICE guideline [NG125] Surgical site infections: prevention and treatment, April 2019
- ⁴ Hygiene Nord GmbH, 2017, Test Report A17050. Available on request.

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