

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Gluconate Solution 20% BP (Ph Eur) 2.5% v/v.

Excipients with known effect:

Denatured Ethanol B 96% (72.9% v/v)

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For pre-operative skin disinfection prior to surgical procedures.

4.2 Posology and method of administration

Add the entire contents of the bottle of RSS to the Prevase Stain, mix well and use immediately 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 3 minutes to ensure adequate microbial reduction.

This product is applied topically. For single use only.

4.3 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 (see sections 4.4 and 4.8).

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.

4.4 Special warnings and precautions for use

Prevase Stain 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 Stain 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).

This medicine includes 110.2g alcohol (ethanol) in each dose of 200ml which is equivalent to 621 mg/g (62.1 %w/w), 551 mg/ml (55.1 %w/v). In neonates (pre-term and term newborn infants), high concentrations of ethanol may cause severe local reactions and systemic toxicity due to significant absorption through immature skin (especially under occlusion).

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 antiseptics 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 Stain, care must be taken to ensure no excess product is present prior to application of the dressing.

Prevase Stain must not come into contact with the eye. Serious cases of persistent corneal injury, potentially requiring corneal transplant, were reported following accidental ocular exposure to chlorhexidine containing medicinal products despite taking eye protective measure due to migration of solution beyond the intended surgical preparation area. Extreme care must be taken during application to ensure that Prevase Stain does not migrate beyond its intended application site into the eyes. Particular care should be taken in anaesthetised patients, who are unable to immediately report ocular exposure. If Prevase Stain comes into contact with the eyes, wash out promptly and thoroughly with water. An ophthalmologist's advice should be sought.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Fertility, pregnancy and lactation

None stated.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Immune disorders

Frequency not known:

- Hypersensitivity including anaphylactic shock (see sections 4.3 and 4.4).

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

Eye Disorder

Frequency not known:

- Corneal erosion, epithelium defect/corneal injury, significant permanent visual impairment*

System organ class	Very common (≥1/10)	Common (≥1/100 <1/10)	Uncommon (≥1/10,000 <1/1,000)	Rare (≥1/10,000 <1/1,000)	Very rare (<1/10,000)	Not known (cannot be estimated from available data)
Immune system disorders						Hypersensitivity Anaphylactic shock
Skin and subcutaneous tissue disorders						Allergic skin reactions Chemical burns (neonates and infants)
Eye Disorder						Corneal erosion, epithelium defect/corneal injury, significant permanent visual impairment*

*Cases of severe corneal erosion and permanent significant visual impairment due to inadvertent ocular exposure have been reported post-marketing, leading to some patients requiring corneal transplant (see section 4.4).

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

None stated

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

None stated

5.2 Pharmacokinetic properties

None stated

5.3 Preclinical safety data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Denatured Ethanol B 96%

Purified Water

111959 Carmoisine (E122)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

Once the RSS has been added to the Prevasse Stain use immediately.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

Prevasse Stain is packaged in a 200ml natural round HDPE bottle with a white PP and PE screw cap closure.

Red staining solution is packaged in a 5 ml natural round HDPE bottle with a white wadless ribbed HDPE screw cap.

Each box contains 24 x Prevasse stain bottles and 24 x Red Staining solution bottles.

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Ecolab Ltd, Unit 1, Wernddu Court, Caerphilly, CF83 3SG, UK.

8 MARKETING AUTHORISATION NUMBER(S)

PL 04509/0063

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

21/02/2025

10 DATE OF REVISION OF THE TEXT

21/02/2025