

Prescribing Information: ChloraPrep™ and ChloraPrep™ with Tint 2% w/v chlorhexidine gluconate / 70% v/v isopropyl alcohol cutaneous solution; ChloraPrep™ 2% w/v chlorhexidine gluconate / 70% v/v isopropyl alcohol impregnated cutaneous swab. Refer to the Summary of Product Characteristics before prescribing. **Presentation:**

ChloroPrep: 1 mL solution contains 20 mg of chlorhexidine gluconate (20 mg/mL) and 0.70 mL of isopropyl alcohol (0.70 mL/mL).
1 applicator with 1 mL solution contains 20 mg of chlorhexidine gluconate (20 mg/mL) and 0.70 mL of isopropyl alcohol (0.70 mL/mL).
1 applicator with 1.5 mL solution contains 30 mg of chlorhexidine gluconate (20 mg/mL) and 1.05 mL of isopropyl alcohol (0.70 mL/mL).
1 applicator with 3 mL solution contains 60 mg of chlorhexidine gluconate (20 mg/mL) and 2.10 mL of isopropyl alcohol (0.70 mL/mL).
1 applicator with 10.5 mL solution contains 210 mg of chlorhexidine gluconate (20 mg/mL) and 7.35 mL of isopropyl alcohol (0.70 mL/mL).
1 applicator with 26 mL solution contains 520 mg of chlorhexidine gluconate (20 mg/mL) and 18.20 mL of isopropyl alcohol (0.70 mL/mL).
The packaging consists of a lidding material sealed to a polymeric film creating a "pouch-like" packet surrounding the applicator.

ChloroPrep with Tint: 1 mL solution contains 20 mg of chlorhexidine gluconate (20 mg/mL) and 0.70 mL of isopropyl alcohol (0.70 mL/mL).
1 applicator with 3 mL solution contains 60 mg of chlorhexidine gluconate (20 mg/mL) and 2.10 mL of isopropyl alcohol (0.70 mL/mL).
1 applicator with 10.5 mL solution contains 210 mg of chlorhexidine gluconate (20 mg/mL) and 7.35 mL of isopropyl alcohol (0.70 mL/mL).
1 applicator with 26 mL solution contains 520 mg of chlorhexidine gluconate (20 mg/mL) and 18.20 mL of isopropyl alcohol (0.70 mL/mL).
The packaging consists of a lidding material sealed to a polymeric film creating a "pouch-like" packet surrounding the applicator.

ChloroPrep cutaneous swab: each swab of 1.75 mL solution contains 35 mg of chlorhexidine gluconate (20 mg/mL) and 1.23 mL isopropyl alcohol (0.70 mL/mL). Three swabs containing 5.25 mL of solution contains 105 mg of chlorhexidine gluconate (20 mg/mL) and 3.7 mL isopropyl alcohol (0.70 mL/mL).

Indication: Disinfection of the skin prior to invasive medical procedures. **Dosage & administration:** The choice of applicator or swab will depend on the invasive procedure being undertaken. May be used in all age groups and patient populations. Should be used with care in newborn babies, especially those born prematurely. The applicator is squeezed gently to break the ampoule containing the antiseptic solution, which is released onto the sponge in a controlled flow. The sponge is gently pressed against the patient's skin in order to apply the antiseptic solution. Once the solution is visible on the skin, use gentle back and forth strokes to prep the site for 30 seconds. The area covered should be allowed to air dry completely. **Contra-indications:** Known hypersensitivity to ChloroPrep, ChloroPrep with Tint or ChloroPrep cutaneous swab or any of its components, especially those with a history of possible chlorhexidine-related allergic reactions. ChloroPrep cutaneous swab: Use in the ear canal due to the risk of ototoxicity. **Warnings and precautions:** The solution is flammable. The solution is an irritant to mucous membranes. It should be therefore kept away from these areas. Do not use electrocautery procedures or other ignition sources until the skin is completely dry. Remove any soaked materials, drapes or gowns before proceeding with the intervention. Do not use excessive quantities and do not allow 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 ChloroPrep, care must be taken to ensure no excess product is present prior to application of the dressing. For external use only on intact skin. Do not use on open skin wounds. Do not use on broken or damaged skin. In addition, direct contact with neural tissue or the middle ear must be avoided. When the solution has been applied in an over-vigorous manner to very fragile or sensitive skin or after repeated use, local skin reaction may occur. Prolonged skin contact with alcohol containing solutions should be avoided. ChloroPrep 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 measures due to migration of solution beyond the intended surgical preparation area. Extreme care must be taken during application to ensure that ChloroPrep 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 ChloroPrep comes into contact with the eyes, wash out promptly and thoroughly with water. An ophthalmologist's advice should be sought. Chlorhexidine is known to induce hypersensitivity, including generalised allergic reactions and anaphylactic shock. Chlorhexidine-containing products are known causes of anaphylactic reactions during anaesthesia. The symptoms of anaphylactic reactions might be masked in an anaesthetised patient. If symptoms of an anaphylactic reaction are detected during anaesthesia, chlorhexidine related allergic reaction should be considered. When chlorhexidine-related allergic reaction during anaesthesia is suspected, other products containing chlorhexidine used during anaesthesia (e.g. IV lines) should be removed. Special precaution should be taken to avoid patient exposure to any other product containing chlorhexidine during the course of the treatment. 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. 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. **Pregnancy & lactation:** Although no studies have been conducted, no effects are anticipated as systemic exposure is negligible. **Undesirable effects:** Very rarely (<1/10,000); allergic or irritation skin reactions to chlorhexidine, isopropyl alcohol or sunset yellow (E110, present in ChloroPrep with Tint only), including erythema, rash, pruritus and blisters or application site vesicles. Other local symptoms have included skin burning sensation, pain, inflammation. *Frequency not known* (cannot be estimated from the available data); hypersensitivity including anaphylactic shock, dermatitis, eczema, urticaria, chemical burns in neonates, eyes irritation and pain, hyperaemia, 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. At the first sign of local skin reaction application of ChloroPrep should be stopped. Cases of anaphylactic reactions have been reported during anaesthesia. **Description of selected adverse reactions:** There have been isolated spontaneous reports of generalised allergic reactions potentially associated with ChloroPrep solution that have been reported during anaesthesia. In some cases, the patient may have had a pre-existing sensitivity to chlorhexidine. This product may cause a severe allergic reaction. Symptoms may include wheezing/difficulty breathing, shock, facial swelling, hives, or rash. Use of ChloroPrep is contra-indicated where patients have shown previous hypersensitivity to chlorhexidine or isopropyl alcohol (see Section Contra-indications). If hypersensitivity or an allergic reaction occurs, stop use and seek medical help right away. The prescribers should consult the Summary of Product Characteristics in relation to other adverse reactions. **Per applicator costs** (ex VAT) Direct sales, for the UK only. For costs in Ireland contact the Distributor. ChloroPrep 1.75ml (Single swab) – £0.37; ChloroPrep: 1ml – £0.34; 1.5ml (FREPP) – £0.58; 3ml – £0.90; 10.5ml – £3.24; 26ml – £7.21. ChloroPrep with Tint: 3ml – £0.94; 10.5ml – £3.40; 26ml – £7.57.

Legal category: UK: GSL. Ireland: Not subject to medical prescription. **Marketing Authorisation Numbers:** ChloroPrep, (UK: PL05920/0002; Ireland: PA2287/001/002); ChloroPrep with Tint, (UK: PL05920/0003; Ireland: PA2287/001/001); ChloroPrep cutaneous swab (UK: PL05920/0006; Ireland: PA2287/001/003). **Marketing Authorisation Holder:** Becton Dickinson UK Ltd, 1030 Eskdale Road, Winnersh, Wokingham RG41 5TS, United Kingdom. Ireland: Becton Dickinson France, 11 Rue Aristide Bergès, 38800 Le Pont de Claix, France **Date of Revision of the API:** February 2026.

Additional information is available upon request.

Reporting suspected adverse reactions is important to monitor the benefit/risk balance of the medicinal product. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard (for UK) and www.hpra.ie (for Ireland). Customer contact for adverse events and medical information inquiries –For UK: 0800 0437 546, or email: SafetyInformation@bd.com. For Ireland: 1800937570 or email: SafetyInformation@bd.com