COMBINED ESSENTIAL INFORMATION FOR PERSONS QUALIFIED TO PRESCRIBE OR SUPPLY (Full advertisements and loose inserts)	
Name of the product	ChloraPrep and ChloraPrep with Tint
Reference	UK/IE-API-006
Country	UK
Date of preparation	28 July 2023
Revision purpose	Harmonisation with SPC; removal of discontinued formulation; Ireland process, MAH and PV removed

Prescribing Information: ChloraPrep™ and ChloraPrep™ with Tint 2% w/v chlorhexidine gluconate / 70% v/v isopropyl alcohol cutaneous solution. Refer to the Summary of Product Characteristics before prescribing. **Presentation**: ChloraPrep – each applicator contains 1ml, 1.5ml, 3ml, 10.5ml or 26ml of 20 mg/ml chlorhexidine gluconate and 0.70 ml/ml isopropyl alcohol; ChloraPrep with Tint – each applicator contains 3ml, 10.5ml or 26ml of 20 mg/ml chlorhexidine gluconate and 0.70 ml/ml isopropyl alcohol. **Indication**: Disinfection of the skin prior to invasive medical procedures. **Dosage & administration**: The choice of applicator will depend on the invasive procedure being undertaken. May be used for 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 ChloraPrep or ChloraPrep with Tint or any of its components, especially those with a history of possible chlorhexidine-related allergic reactions. **Warnings and precautions:** The solution is flammable. 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 ChloraPrep, 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. The solution is an irritant to eyes and mucous membranes. Chlorhexidine known to induce hypersensitivity, including generalised allergic reactions and anaphylactic shock. Chlorhexidine-containing products are known causes of anaphylactic reactions during anesthesia. The symptoms of anaphylactic reactions might be masked in an anesthetized patient. If symptoms of an anaphylactic reaction are detected during anesthesia, chlorhexidine related allergic reaction should be considered. When chlorhexidine-related allergic reaction during anesthesia is suspected, other products containing chlorhexidine used during anesthesia (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 antisepsis 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 ChloraPrep with Tint only), including erythema, rash, pruritus and blisters or application site vesicles. Other local symptoms have included skin burning sensation, pain and inflammation. *Frequency not known;* hypersensitivity including anaphylactic shock, dermatitis, eczema, urticaria, chemical burns in neonates, eyes irritation and pain, hyperaemia, impaired vision, chemical burn, and eye injury. At the first sign of local skin reaction application of ChloraPrep should be stopped. Cases of anaphylactic reactions have been reported during anesthesia. **Description of selected adverse reactions:** There have been isolated spontaneous reports of generalised allergic reactions potentially associated with ChloraPrep solution and have been reported during anesthesia. 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 ChloraPrep 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. **Per applicator costs** (ex VAT) ChloraPrep: 1ml – £0.32; 1.5ml (FREPP) - £0.55; 3ml – £0.85; 10.5ml - £2.92; 26ml – £6.50. ChloraPrep with Tint: 3ml – £0.89; 10.5ml – £3.07; 26ml – £6.83 **Legal category**: GSL. **Marketing Authorisation Numbers:** ChloraPrep PL05920/0002-001; ChloraPrep with Tint PL05920/0003-0001. **Marketing Authorisation Holder**: Becton Dickinson UK Ltd, 1030 Eskdale Road, Winnersh, Wokingham RG41 5TS, United Kingdom. **Date of Revision of the API:** July 2023

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