

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

ChloroPrep with Tint 2% w/v / 70% v/v cutaneous solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine gluconate 20mg/ml

Isopropyl alcohol 0.70ml/ml

For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Cutaneous Solution.

Orange Solution.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

The medicinal product is to be used for disinfection of the skin prior to invasive medical procedures.

### 4.2 Posology and method of administration

Posology

ChloroPrep with Tint may be used in all age groups and patient populations (see section on paediatric population, below).

*Paediatric population*




ChloroPrep with Tint should be used with care in newborn babies, especially those born prematurely (see also section 4.4, Special warnings and precautions for use).

Method of administration

For cutaneous use.

One applicator is used containing 3 mL, 10.5 mL or 26 mL of the ChloroPrep with Tint alcoholic solution.

The choice of applicator will depend on the invasive procedure being undertaken and the clinician's preference.

Applicator	Coverage Area (cm x cm)	For Procedures such as:
<b>3 mL</b> 	15 x 15	<ul style="list-style-type: none"> <li>- Midline &amp; Central Venous Catheter (CVC) insertion and maintenance</li> <li>- Peritoneal dialysis site cleansing</li> </ul>
<b>10.5 mL</b> 	25 x 30	<ul style="list-style-type: none"> <li>- Minor and major surgical procedures</li> <li>- Implantable device placement</li> <li>- Prosthetic device placement or removal</li> <li>- Midline, Peripheral Intravascular Central Catheter (PICC) &amp; CVC insertion and maintenance</li> <li>- Cardiac catheterisation and Cardiac Cath Lab procedures</li> <li>- Interventional Radiology procedure</li> </ul>
<b>26 mL</b> 	50 x 50	

The applicator is removed from the wrapper and held with the sponge facing downward. The applicator is squeezed gently to break the ampoule containing the antiseptic solution, which is released onto the sponge in a controlled flow (for the 26 mL applicator the lever is pressed). Pinch wings **once only** to activate the applicator and release the antiseptic. Do not repeatedly pinch or pump the wings in an attempt to accelerate the saturation of the foam. The broken ampoule remains safely contained within the applicator. 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 prepare the site for 30 seconds. The 26 mL applicator includes two swabs. The area covered should be allowed to air dry completely.

It is recommended that ChloroPrep with Tint remain on the skin post-procedure to provide continued antimicrobial activity. The tint will slowly fade from the skin. If removal is necessary, remove with soap and water or alcohol.

#### 4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients 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

**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 of ChloroPrep with Tint 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 ChloroPrep with Tint, care must be taken to ensure no excess product is present prior to application of the dressing.

For external use only on intact skin.

ChloroPrep with Tint 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. ChloroPrep with Tint should not be administered to anyone with a potential history of an

allergic reaction to a chlorhexidine-containing compound (see sections 4.3 and 4.8). The solution is an irritant to mucous membranes. It should therefore be kept away from these areas.

ChlorPrep with Tint 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 ChlorPrep with Tint 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 ChlorPrep with Tint comes into contact with the eyes, wash out promptly and thoroughly with water. An ophthalmologist's advice should be sought.

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.

Prolonged skin contact with alcohol containing solutions should be avoided.

It is important to ensure that the correct method of application is strictly followed (see section 4.2 above). 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 including: erythema or inflammation, itching, dry and/or flaky skin and local application site pain. At the first sign of local skin reaction, application of ChlorPrep with Tint should be stopped.

### **Anaphylactic reactions during anaesthesia**

Chlorhexidine-containing products are known causes of anaphylactic reactions during anaesthesia.

The symptoms of anaphylactic reactions might be masked in an anaesthetised patient e.g. a significant portion of skin may be covered or patient unable to communicate early symptoms.

If symptoms of an anaphylactic reaction are detected during anaesthesia (e.g. abrupt fall in blood pressure, hives, angioedema), 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.

### Paediatric population

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, 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.

## **4.5 Interaction with other medicinal products and other forms of interaction**

Alcohol should not be brought into contact with some vaccines and skin test injections (patch tests). If in doubt, consult the vaccine manufacturer's literature.

## **4.6 Fertility, pregnancy and lactation**

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

### Pregnancy

No effects during pregnancy are anticipated, since systemic exposure to chlorhexidine gluconate is negligible. ChlorPrep with Tint can be used during pregnancy.

### Breastfeeding

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to chlorhexidine gluconate is negligible. ChlorPrep with Tint can be used during breast-feeding.

### Fertility

The effects of chlorhexidine gluconate on human reproduction have not been studied.

## **4.7 Effects on ability to drive and use machines**

ChlorPrep with Tint has no or negligible influence on the ability to drive and use machines.

## 4.8 Undesirable effects

### Skin and subcutaneous tissue disorders:

Very rarely (<1/10,000) allergic or irritation skin reactions have been reported with chlorhexidine, isopropyl alcohol and Sunset Yellow (E110) 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 not known (cannot be estimated from the available data): dermatitis, eczema, urticaria, chemical burns in neonates.

### Immune system disorders:

Frequency not known (cannot be estimated from the available data): Hypersensitivity including anaphylactic shock (see sections 4.3 and 4.4).

The most commonly reported adverse reactions reported are associated with application site reactions. These were noted to occur most often within the area of application of the solution (i.e. at skin the preparation site) and very rarely spread. The adverse reactions were often self-limiting in nature or resolved following treatment with topical steroids and / or antihistamines. The most commonly reported reactions were non-serious in nature and included 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 as in adults.

Cases of anaphylactic reactions have been reported during anaesthesia.

### Eye disorders:

Frequency not known (cannot be estimated from the available data): Eye irritation, 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 (see section 4.4).

### Description of selected adverse reactions

There have been isolated spontaneous reports of generalised allergic reactions potentially associated with ChlorPrep solution that have been reported during anaesthesia. In some cases, the patient may have had a pre-existing sensitivity to chlorhexidine (see Section 4.4).

This product may cause a severe allergic reaction. Symptoms may include wheezing/difficulty breathing, shock, facial swelling, hives, or rash. Use of ChlorPrep with Tint is contra-indicated where patients have shown previous hypersensitivity to chlorhexidine or isopropyl alcohol (see Section 4.3). If hypersensitivity or an allergic reaction occurs, stop use and seek medical help right away.

### 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:

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

## 4.9 Overdose

There are no reports of overdose with this product.

## 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. It has a superior residual property in comparison to currently available skin antiseptics. Chlorhexidine gluconate has a strong binding property to skin and has a residual property on the skin that has been documented at 48 hours. 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.

#### Pharmacodynamic effects

ChloraPrep with Tint is a sterile 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 efficacy and safety

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.

ChloraPrep with Tint meets the criteria for chemical disinfectants and antiseptic products as established by European Standards:

EN 1040 - basic bactericidal activity (Phase 1)

EN 1275 - basic yeasticidal activity (Phase 1)

EN 13727 - bactericidal activity (Phase 2/Step 1)

EN 13624 - fungicidal activity (Phase 2/Step 1)

ChloraPrep with Tint meets these EN criteria for bactericidal and fungicidal activity for the following organisms at contact times ranging from 5 to 15 minutes, with the exception of *Aspergillus brasiliensis*. Additional testing of ChloraPrep with Tint at full concentration against *Aspergillus brasiliensis* for exposure up to 60 minutes met EN 13624 criteria, as follows:

Table: In vitro microbiocidal effects

Strain	Contact time	Conditions	Result	EN Criteria
<i>Pseudomonas aeruginosa</i>	5 min	100%, 75%, 50%	>5.69 log reduction	EN 1040
<i>Staphylococcus aureus</i>	5 min	100%, 75%, 50%	>4.67 log reduction	EN 1040
<i>Candida albicans</i>	15 min	100%, 75%, 50%	> 4.25 log reduction	EN 1275
<i>Enterococcus hirae</i>	5 min	100%, 75%, 50% in clean 0.3 g/L bovine serum albumin	> 5.71 log reduction	EN 13727
<i>Pseudomonas aeruginosa</i>	5 min	100%, 75%, 50% in clean 0.3 g/L bovine serum albumin	> 5.55 log reduction	EN 13727
<i>Staphylococcus aureus</i>	5 min	100%, 75%, 50% in clean 0.3 g/L bovine serum albumin	> 5.78 log reduction	EN 13727
<i>Candida albicans</i>	15 min	100%, 75%, 50% in clean 0.3 g/L bovine serum albumin	> 4.17 log reduction	EN 13624
<i>Aspergillus brasiliensis</i>	60 min	100%	> 4.26 log reduction	EN 13624

## 5.2 Pharmacokinetic properties

### Absorption

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

There are no preclinical data of relevance to the prescriber that are not already included elsewhere in the Summary of Product Characteristic.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Purified water  
Sunset Yellow (E110)

### **6.2 Incompatibilities**

Chlorhexidine is incompatible with soap, hypochlorite bleach and other anionic agents. Hypochlorite bleaches may cause brown stains to develop in fabrics, which have previously been in contact with preparations containing chlorhexidine.

### **6.3 Shelf life**

3 years

### **6.4 Special precautions for storage**

Flammable. This medicinal product does not require any special temperature storage conditions. Store in the original packaging; applicator is sterile unless seal is broken. Avoid exposure of the container and contents to naked flames during use, storage and disposal.

### **6.5 Nature and contents of container**

The applicators consist of a latex-free sponge attached to a plastic handle/barrel which holds a latex-free dyed pledget and glass ampoule containing the sterile antiseptic solution. The 3 ml and 10.5 ml applicators consist of a latex-free round foam sponge attached to a plastic barrel which holds a glass ampoule containing the antiseptic solution. The 26 ml applicator consists of a latex-free square foam sponge attached to a plastic barrel which holds two glass ampoules containing the antiseptic solution. The sterile applicators are individually packaged in a transparent film.

The medicinal product is available as 3 ml, 10.5 ml and 26 ml fill volumes.

Pack Size:

3 ml: 1 applicator or 25 applicators  
10.5 ml: 1 applicator or 25 applicators  
26 ml: 1 applicator

Not all pack sizes may be marketed.

### **6.6 Special precautions for disposal and other handling**

This product is for single use only.

Any unused product or waste material should be discarded in accordance with local requirements. No additional environmental precautions for disposal are necessary.

## **7 MARKETING AUTHORISATION HOLDER**

Becton Dickinson France  
11 Rue Aristide Bergès  
38800 Le Pont de Claix  
France

## **8 MARKETING AUTHORISATION NUMBER**

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

Date of first authorisation: 2<sup>nd</sup> July 2010

Date of last renewal: 27<sup>th</sup> November 2014

**10 DATE OF REVISION OF THE TEXT**

January 2026