

ChloroPrep® with Tint

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 20 mg/ml

Isopropyl alcohol 0.70 ml/ml

For a 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

For cutaneous use.

ChloroPrep with Tint may be used on all age groups and patient populations. However, ChloroPrep with Tint is not recommended for children younger than 2 months old.

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.

3 ml applicator		For procedures such as: <ul style="list-style-type: none">- Midline & Central Venous Catheter (CVC) insertion and maintenance- Peritoneal dialysis site cleansing		
10.5 ml applicator		26 ml applicator		For procedures such as: <ul style="list-style-type: none">- Minor and major surgical procedures- Implantable device placement- Prosthetic device placement or removal- Midline, Peripheral Intravascular Central Catheter (PICC) & CVC insertion and maintenance- Cardiac catheterisation and cardiac cath lab procedures- Interventional radiology procedure

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). 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. A back and forth action of the sponge should be used for 30 seconds. The 26 ml applicator includes two swabs. Clean umbilicus with enclosed swabs when applicable. (Moisten swabs by pressing against solution-soaked sponge applicator.) The area covered should be allowed to dry naturally.

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

The medicinal product is contra-indicated where patients have shown previous hypersensitivity to chlorhexidine, isopropyl alcohol or Sunset Yellow [E110].

4.4 Special warnings and precautions for use

For external use only on intact skin.

The solution is an irritant to eyes and mucous membranes. It should therefore be kept away from these areas. If the solution comes in contact with the eyes, they should be washed promptly and thoroughly with water.

It should also not be used on open skin wounds, broken or damaged skin, or in children less than 2 months of age. In addition, direct contact with neural tissue or the middle ear must be avoided.

Prolonged skin contact with alcoholic solutions should be avoided.

The solution is flammable. Do not use with electrocautery procedures or other ignition sources until dry.

Remove any soaked materials, drapes or gowns before proceeding. Do not allow the solution to pool.

It is important to ensure that the correct method of applications 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 ChloroPrep with Tint should be stopped.

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 Pregnancy and lactation

There are no known risks for the use of this product in pregnant or lactating women.

4.7 Effects on ability to drive and use machines

No effects are reported.

4.8 Undesirable effects

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.

At the first sign of local skin reaction application of ChlorPrep with Tint should be stopped.

4.9 Overdose

There are no reports of overdose with this product.

5 Pharmacological properties

5.1 Pharmacodynamic properties

ATC code D08A C52 (Chlorhexidine, combinations).

Mode of Action: Bisbiguanide antiseptics exert their lethal effect upon bacterial cells through non-specific interaction with acidic phospholipids of the cell membranes.

Chlorhexidine is both an antiseptic and disinfectant that is bactericidal or bacteriostatic against a wide range of gram-positive and gram-negative bacteria. It is more effective against Gram-positive than Gram-negative bacteria, and some species of *Pseudomonas* and *Proteus* have low susceptibility. It is relatively ineffective against mycobacteria. It inhibits some viruses and is active against some fungi. It is inactive against bacterial spores at room temperature. Combinations in alcoholic solution are used to enhance efficacy. It should also be stated that isopropyl alcohol is bacteriostatic at low concentrations but has bactericidal activity at higher concentrations; it does not, however, destroy bacterial spores. The mechanism of action appears to be denaturation of proteins.

Since there is little percutaneous absorption of isopropyl alcohol or chlorhexidine gluconate and the medicinal product is indicated for use on pre-injection sites, pharmacodynamic studies have not been undertaken.

5.2 Pharmacokinetic properties

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 SPC.

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

18 months

6.4 Special precautions for storage

Flammable. Do not store above 25°C.

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

ChloraPrep with Tint is a sterile alcoholic antiseptic solution containing chlorhexidine gluconate and isopropyl alcohol in an applicator. 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 antiseptic solution. The 3 ml and 10.5 ml applicators each have a single glass ampoule within the plastic barrel. The 26 ml applicator holds two 13 ml glass ampoules. The sterile applicators are individually packaged in an ethyl vinyl acetate film.

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

Pack Size:

3 ml: 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

The solution is flammable. Do not use while smoking, or near any naked flames or strong heat source.

Avoid exposure of the container and contents to naked flames during use, storage and disposal.

This product is for single use only.

Any unused product or waste material should be discarded in accordance with local requirements.

7 Marketing authorisation holder

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8 Marketing authorisation number(s)

PL 31760/0001

9 Date of first authorisation/renewal of the authorisation

23 Dec 2009

10 Date of revision of the text

12/2009