ChloraPrep®
Summary of Product Characteristics

1 Name of the medicinal product

ChloraPrep® One-Step 2% chlorhexidine gluconate w/v / 70% isopropyl alcohol v/v cutaneous solution.

2 Qualitative and quantitative composition

Chlorhexidine gluconate 2.0% w/v
Isopropyl alcohol 70% v/v
For excipients see 6.1

3 Pharmaceutical form

Cutaneous Solution.
The solution appears as a clear liquid having an odour of alcohol.

4 Clinical particulars

4.1 Therapeutic indications

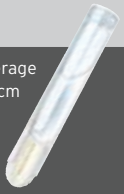
The medicinal product is to be used for disinfection of the skin prior to invasive procedures.

4.2 Posology and method of administration

For cutaneous use.

One applicator is used containing 0.67 ml, 1.5 ml, 3 ml, 10.5 ml or 26 ml of the ChloraPrep alcoholic solution. The choice of applicator will depend on the invasive procedure being undertaken and the clinician's preference.

SEPP .67ml	For procedures such as:
Maximum coverage area 5 cm x 8 cm	- Peripheral cannulation - Simple biopsy - Routine venipuncture



1.5ml applicator	FREPP 1.5ml	For procedures such as:
Maximum coverage area 10 cm x 13 cm	Maximum coverage area 10 cm x 13 cm	- Blood culture collection - Peripheral cannulation - Peripheral arterial line cannulation - Simple biopsy - Routine venipuncture - Dialysis Fistula/Graft site cleansing

3ml applicator

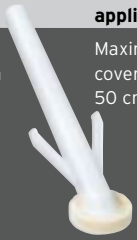
Maximum coverage area 15 cm x15 cm

For procedures such as:

- Midline & Central Venous Catheter (CVC) insertion and maintenance
- Peritoneal dialysis site cleansing

10.5ml applicator

Maximum coverage area 25 cm x30 cm



26ml applicator

Maximum coverage area 50 cm x 50cm

For procedures such as:

- 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 0.67 ml the barrel is squeezed; 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.

4.3 Contraindications

The medicinal product is contra-indicated where patients have shown previous hypersensitivity to chlorhexidine or isopropyl alcohol.

4.4 Special warnings and precautions for use

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, for lumbar puncture or in children less than 2 months of age. In addition, contact with the brain, meninges and middle ear must be avoided.

Prolonged skin contact with alcoholic solutions should be avoided.

Rarely allergic or irritation skin reactions have been reported with chlorhexidine.

For external use only.

Do not use with electrocautery procedures until dry. Remove any soaked materials, drapes or gowns before proceeding.

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 manufacturers literature.

4.6 Pregnancy and lactation
There are no studies with this product in pregnant or lactating women. However as percutaneous absorption is negligible, there is no reason why this product may not be used during pregnancy or by breast feeding mothers.

4.7 Effects on ability to drive and use machines
No effects are reported.

4.8 Undesirable effects
Rarely allergic or irritation skin reactions have been reported with chlorhexidine and isopropyl alcohol.

4.9 Overdose
There are no reports of this occurring and the nature of the product makes it unlikely.

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.

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.

6.2 Incompatibilities
Chlorhexidine is incompatible with soap and other anionic agents.

6.3 Shelf life
24 months.

6.4 Special precautions for storage
Do not store above 25°C.
Avoid freezing.
Store in the original packaging.

6.5 Nature and contents of container

The alcoholic solution is contained in a borosilicate Type 1 glass ampoule which is housed in an applicator.

The applicator consists of a HDPE plastic handle/barrel containing the ampoule with the ChloraPrep solution. For the 1.5 ml (both the FREPP and standard applicator) and 3 ml, 10.5 ml and 26 ml applicators, the handle is bonded to a Novonette film and a polyester urethane foam. For the 0.67 ml SEPP applicator, the barrel is bonded to the polyester urethane foam which is stitch-bonded to a polyester airweave.

The applicator is wrapped in an ethyl vinyl acetate film.

The medicinal product is available as 0.67 ml, 1.5 ml, 3 ml, 10.5 ml and 26 ml fill volumes.

Pack Size:

0.67 ml (SEPP):	200 applicators
1.5 ml (FREPP):	20 applicators
1.5 ml and 3 ml:	25 applicators
10.5 ml:	1 applicator or 25 applicators
26 ml:	1 applicator

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. Discard after use as per clinical waste procedures.

7 Marketing authorisation holder

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8 Marketing authorisation number(s)

PL 31760/0002

9 Date of first authorisation/renewal of the authorisation

26/02/2008

10 Date of revision of the text

02/04/2008

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