Version 1.4, 02/2016

SUMMARY OF PRODUCT CHARACTERISTICS,
LABELLING AND PACKAGE LEAFLET

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

ChloraPrep 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 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
ChloraPrep with Tint may be used on all age groups and patient populations.

Paediatric population
However, ChloraPrep 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).

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

Method of administration
For cutaneous use.

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:
3 ml 	15 x 15	- Midline & Central Venous Catheter (CVC) insertion and maintenance - Peritoneal dialysis site cleansing
10.5 ml  **26 ml** 	25 x 30 50 x 50	- 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). 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 prep the site for 30 seconds. The 26 ml applicator includes two swabs. Clean intact umbilicus with enclosed swabs when applicable. (Moisten swabs by pressing against solution-soaked sponge applicator.) The area covered should be allowed to air dry completely.

It is recommended that ChloraPrep 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

Known hypersensitivity to ChloraPrep with Tint or any of its components, 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 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 ChloraPrep 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.

ChloraPrep 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. ChloraPrep 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.

ChloraPrep 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 ChloraPrep 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 ChloraPrep 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 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 ChloraPrep 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 anesthetized 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. ChloraPrep 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. ChloraPrep 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

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

4.8 Undesirable effects

Skin 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: dermatitis, eczema, urticaria, chemical burns in neonates.

Immune disorders:
Frequency not known: 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 the prep 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: 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 ChloraPrep solution and 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 ChloraPrep 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
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@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**
Pseudomonas aeruginosa	5 min	100%, 75%, 50%	> 5.69 log reduction	EN 1040
Staphylococcus aureus	5 min	100%, 75%, 50%	> 4.67 log reduction	EN 1040
Candida albicans	15 min	100%, 75%, 50%	> 4.25 log reduction	EN 1275
Enterococcus hirae	5 min	100%, 75%, 50% in clean 0.3 g/L bovine serum albumin	> 5.71 log reduction	EN 13727
Pseudomonas aeruginosa	5 min	100%, 75%, 50% in clean 0.3 g/L bovine serum albumin	> 5.55 log reduction	EN 13727
Staphylococcus aureus	5 min	100%, 75%, 50% in clean 0.3 g/L bovine serum albumin	> 5.78 log reduction	EN 13727
Candida albicans	15 min	100%, 75%, 50% in clean 0.3 g/L bovine serum albumin	> 4.17 log reduction	EN 13624
Aspergillus brasiliensis	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 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

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(S)

PA2287/001/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd July 2010

Date of last renewal: 27th November 2014

10. DATE OF REVISION OF THE TEXT

June 2024

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON – 3 ml Applicator

1. NAME OF THE MEDICINAL PRODUCT

ChloraPrep with Tint 2% w/v / 70% v/v Cutaneous Solution

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Chlorhexidine Gluconate 20 mg/ml
Isopropyl Alcohol 0.70 ml/ml

3. LIST OF EXCIPIENTS

Also contains: Purified water, Sunset Yellow (E110)

4. PHARMACEUTICAL FORM AND CONTENTS

Cutaneous solution. Orange solution.

The applicators consist of a latex-free round sponge attached to a plastic handle/barrel which holds a latex-free dyed pledget and glass ampoule containing the antiseptic solution.

25 applicators (3 ml solution per applicator)

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For cutaneous use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

For external and single use only.
Do not use on broken or damaged skin.
Use with care in newborn babies, especially those born prematurely. ChloraPrep with Tint may cause chemical skin burns.
Do not use electrocautery procedures until the skin is completely dry.

8. EXPIRY DATE

EXP: MM/YYYY

9. SPECIAL STORAGE CONDITIONS

Flammable. 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, or disposal.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder (MAH):
Becton Dickinson France
11 Rue Aristide Bergès,
38800 Le Pont de Claix,
France
1800937570

12. MARKETING AUTHORISATION NUMBER(S)

PA2287/001/001

13. BATCH NUMBER

Batch XXXXX

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription

15. INSTRUCTIONS ON USE

Directions: Refer to leaflet for further information. Hold sponge facing downward. Squeeze the wings gently **once only** to break the ampoule. Do not repeatedly pinch or pump the wings in an attempt to accelerate the saturation of the foam. To saturate the sponge, press it against the treatment area and use a gentle back and forth motion for 30 seconds. Allow to air dry completely. Maximum coverage area: 15 cm x 15 cm. For any information about this medicinal product, contact the Marketing Authorisation Holder (MAH).

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

Not applicable

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LIDDING – 3 ml Applicator provided as multiple units

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

ChloraPrep with Tint 2% w/v / 70% v/v Cutaneous Solution
Chlorhexidine Gluconate 20 mg/ml
Isopropyl Alcohol 0.70 ml/ml

2. METHOD OF ADMINISTRATION

For cutaneous use.

3. EXPIRY DATE

EXP: MM/YYYY

4. BATCH NUMBER

Batch XXXXX

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

3 ml

6. OTHER

Read the package leaflet before use.
Also contains Purified water, Sunset Yellow (E110)

For external and single use only. Do not use on broken or damaged skin. Keep out of the sight and reach of children.

Flammable. Do not use with electrocautery procedures until dry. 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 or disposal.

Directions: Refer to leaflet for further information. Remove applicator from wrapper. Hold sponge facing downward. Squeeze the wings gently to break the ampoule. To saturate the sponge, press it against the treatment area and use a back and forth motion for 30 seconds. Allow to dry naturally. Maximum coverage area: 15cm x 15cm.

Cutaneous Solution. Orange Solution.

Marketing Authorisation Holder (MAH):
Becton Dickinson France
11 Rue Aristide Bergès,
38800 Le Pont de Claix,
France
1800937570

PA2287/001/001

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

LIDDING – 3 ml Applicator provided as single unit

1. NAME OF THE MEDICINAL PRODUCT

ChloraPrep with Tint 2% w/v / 70% v/v Cutaneous Solution

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Chlorhexidine Gluconate 20 mg/ml
Isopropyl Alcohol 0.70 ml/ml

3. LIST OF EXCIPIENTS

Also contains: Purified water, Sunset Yellow (E110)

4. PHARMACEUTICAL FORM AND CONTENTS

Cutaneous solution. Orange solution.

The applicators consist of a latex-free round sponge attached to a plastic handle/barrel which holds a latex-free dyed pledget and glass ampoule containing the antiseptic solution.

1 applicator (3 ml solution per applicator)

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For cutaneous use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

For external and single use only.
Do not use on broken or damaged skin.
Use with care in newborn babies, especially those born prematurely. ChloraPrep with Tint may cause chemical skin burns.
Do not use electrocautery procedures until the skin is completely dry.

8. EXPIRY DATE

EXP: MM/YYYY

9. SPECIAL STORAGE CONDITIONS

Flammable. 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, or disposal.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder (MAH):
Becton Dickinson France
11 Rue Aristide Bergès,
38800 Le Pont de Claix,
France
1800937570

12. MARKETING AUTHORISATION NUMBER(S)

PA2287/001/001

13. BATCH NUMBER

Batch XXXXX

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription

15. INSTRUCTIONS ON USE

Directions: Refer to leaflet for further information. Hold sponge facing downward. Squeeze the wings gently **once only** to break the ampoule. Do not repeatedly pinch or pump the wings in an attempt to accelerate the saturation of the foam. To saturate the sponge, press it against the treatment area and use a gentle back and forth motion for 30 seconds. Allow to air dry completely. Maximum coverage area: 15 cm x 15 cm. For any information about this medicinal product, contact the Marketing Authorisation Holder (MAH).

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

Not applicable

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON – 10.5 ml Applicators

1. NAME OF THE MEDICINAL PRODUCT

ChloraPrep with Tint 2% w/v / 70% v/v Cutaneous Solution

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Chlorhexidine Gluconate 20 mg/ml
Isopropyl Alcohol 0.70 ml/ml

3. LIST OF EXCIPIENTS

Also contains: Purified water, Sunset Yellow (E110)

4. PHARMACEUTICAL FORM AND CONTENTS

Cutaneous solution. Orange solution.

The applicators consist of a latex-free round sponge attached to a plastic handle/barrel which holds a latex-free dyed pledget and glass ampoule containing the antiseptic solution.

25 applicators (10.5 ml solution per applicator)

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For cutaneous use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

For external and single use only.
Do not use on broken or damaged skin.
Use with care in newborn babies, especially those born prematurely. ChloraPrep with Tint may cause chemical skin burns
Do not use electrocautery procedures until the skin is completely dry.

8. EXPIRY DATE

EXP: MM/YYYY

9. SPECIAL STORAGE CONDITIONS

Flammable. 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, or disposal.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder (MAH):
Becton Dickinson France
11 Rue Aristide Bergès,
38800 Le Pont de Claix,
France
1800937570

12. MARKETING AUTHORISATION NUMBER(S)

PA2287/001/001

13. BATCH NUMBER

Batch XXXXX

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription

15. INSTRUCTIONS ON USE

Directions: Refer to leaflet for further information. Hold sponge facing downward. Squeeze the wings gently **once only** to break the ampoule. Do not repeatedly pinch or pump the wings in an attempt to accelerate the saturation of the foam. To saturate the sponge, press it against the treatment area and use a gentle back and forth motion for 30 seconds. Allow to air dry completely. Maximum coverage area: 25 cm x 30 cm. For any information about this medicinal product, contact the Marketing Authorisation Holder (MAH).

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

Not applicable

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LIDDING – 10,5 ml Applicator provided as multiple units

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

ChloraPrep with Tint 2% w/v / 70% v/v Cutaneous Solution
Chlorhexidine Gluconate 20 mg/ml
Isopropyl Alcohol 0.70 ml/ml

2. METHOD OF ADMINISTRATION

For cutaneous use.

3. EXPIRY DATE

EXP: MM/YYYY

4. BATCH NUMBER

Batch XXXXX

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

10,5 ml

6. OTHER

Read the package leaflet before use.
Also contains Purified water, Sunset Yellow (E110)

Keep out of the sight and reach of children.
For external and single use only. Do not use on broken or damaged skin. Use with care in newborn babies, especially those born prematurely. ChloraPrep with Tint may cause chemical skin burns. Do not use electrocautery procedures until the skin is completely dry.

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

Directions: Refer to leaflet for further information. Remove applicator from wrapper. Hold the applicator with the sponge facing downward. Squeeze the wings gently **once only** to break the ampoule. Do not repeatedly pinch or pump the wings in an attempt to accelerate the saturation of the foam. To saturate the sponge, press it against the treatment area and use a gentle back and forth motion for 30 seconds. Allow to air dry completely. Maximum coverage area: 25cm x 30cm. For any information about this medicinal product, contact the Marketing Authorisation Holder (MAH).

Cutaneous Solution. Orange Solution.

Marketing Authorisation Holder (MAH):
Becton Dickinson France
11 Rue Aristide Bergès,
38800 Le Pont de Claix,
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1800937570

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

LIDDING – 10.5 ml Applicator provided as single unit

1. NAME OF THE MEDICINAL PRODUCT

ChloraPrep with Tint 2% w/v / 70% v/v Cutaneous Solution

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Chlorhexidine Gluconate 20 mg/ml
Isopropyl Alcohol 0.70 ml/ml

3. LIST OF EXCIPIENTS

Also contains: Purified water, Sunset Yellow (E110)

4. PHARMACEUTICAL FORM AND CONTENTS

Cutaneous solution. Orange solution

The applicators consist of a latex-free round sponge attached to a plastic handle/barrel which holds a latex-free dyed pledget and glass ampoule containing the antiseptic solution

1 applicator (10.5 ml solution per applicator)

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For cutaneous use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

For external and single use only.
Do not use on broken or damaged skin.
Use with care in newborn babies, especially those born prematurely. ChloraPrep with Tint may cause chemical skin burns.
Do not use electrocautery procedures until the skin is completely dry.

8. EXPIRY DATE

EXP: MM/YYYY

9. SPECIAL STORAGE CONDITIONS

Flammable. 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, or disposal.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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12. MARKETING AUTHORISATION NUMBER(S)

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13. BATCH NUMBER

Batch XXXXX

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription

15. INSTRUCTIONS ON USE

Directions: Refer to leaflet for further information. Hold the applicator with the sponge facing downward. Squeeze the wings gently **once only** to break the ampoule. Do not repeatedly pinch or pump the wings in an attempt to accelerate the saturation of the foam. To saturate the sponge, press it against the treatment area and use a gentle back and forth motion for 30 seconds. Allow to air dry completely. Maximum coverage area: 25 cm x 30 cm. For any information about this medicinal product, contact the Marketing Authorisation Holder (MAH).

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

Not applicable

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

LIDDING – 26 ml Applicator provided as single unit

1. NAME OF THE MEDICINAL PRODUCT

ChloraPrep with Tint 2% w/v / 70% v/v Cutaneous Solution

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Chlorhexidine Gluconate 20 mg/ml
Isopropyl Alcohol 0.70 ml/ml

3. LIST OF EXCIPIENTS

Also contains: Purified water, Sunset Yellow (E110)

4. PHARMACEUTICAL FORM AND CONTENTS

Cutaneous solution. Orange solution

1 applicator (26 ml solution per applicator)

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For cutaneous use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

For external and single use only.
Do not use on broken or damaged skin.
Use with care in newborn babies, especially those born prematurely. ChloraPrep with Tint may cause chemical skin burns.
Do not use electrocautery procedures until the skin is completely dry.

8. EXPIRY DATE

EXP: MM/YYYY

9. SPECIAL STORAGE CONDITIONS

Flammable. 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, or disposal.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder (MAH):
Becton Dickinson France
11 Rue Aristide Bergès,
38800 Le Pont de Claix,
France
1800937570

12. MARKETING AUTHORISATION NUMBER(S)

PA2287/001/001

13. BATCH NUMBER

Batch XXXXX

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription

15. INSTRUCTIONS ON USE

Directions: Refer to leaflet for further information. Remove applicator from wrapper. Hold the applicator with the sponge facing downward. Squeeze the lever gently **once only** to break the ampoule. Do not repeatedly pinch or pump the lever in an attempt to accelerate the saturation of the foam. To saturate the sponge, press it against the treatment area and use a gentle back and forth motion for 30 seconds. Allow to air dry completely. Clean intact umbilicus with enclosed swabs when applicable. Moisten swabs by pressing against soaked sponge. Maximum coverage area: 50 cm x 50 cm. For any information about this medicinal product, contact the Marketing Authorisation Holder (MAH).

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

Not applicable

PACKAGE LEAFLET

Package leaflet: Information for the user

ChloraPrep with Tint 2% w/v / 70% v/v Cutaneous Solution

Chlorhexidine Gluconate / Isopropyl Alcohol

3 ml / 10.5 ml / 26 ml

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What ChloraPrep with Tint is and what it is used for

ChloraPrep with Tint is a cutaneous solution of chlorhexidine gluconate 2% w/v and isopropyl alcohol 70% v/v in a plastic applicator with a sponge tip on one end. The applicator contains a fast acting antiseptic solution, which is used to disinfect the skin and help prevent infections before invasive medical procedures, such as injections, insertion of catheters and minor or major surgery. ChloraPrep with Tint contains a tint to colour the skin, which plays no role in the antiseptic properties of the solution.

2. What you need to know before you use ChloraPrep with Tint

Do not use ChloraPrep with Tint:
- if you are allergic (hypersensitive) to chlorhexidine gluconate or any of the other ingredients of ChloraPrep with Tint, especially if you have a history of possible chlorhexidine-related allergic reactions (see Section 6).

Warnings and precautions
ChloraPrep with Tint is for external use only.
ChloraPrep with Tint should not be used:
- near delicate linings (mucous membranes), as it may cause irritation. If it does get into the delicate linings to the body passages, it should be washed quickly with plenty of water.
- on open skin wounds.
- on the part of the ear that is inside the body (middle ear).
- in direct contact with neural tissue (for example brain and spinal cord tissue).

ChloraPrep with Tint must not come into contact with the eye due to the risk of visual damage. If it comes into contact with the eyes, wash out immediately and thoroughly with water. In case of any irritation, redness or pain in the eye, or visual disturbance, ask for medical advice promptly.

Serious cases of persistent corneal injury (injury to the surface of the eye) potentially requiring corneal transplant have been reported when similar products have accidentally come in contact with the eye during surgical procedures, in patients under general anaesthesia (deep painless sleep).

ChloraPrep with Tint may in rare cases cause severe allergic reactions, leading to a drop in blood pressure and even to unconsciousness. Early symptoms of a severe allergic reaction may be skin rash or asthma. If you notice these symptoms, stop using ChloraPrep with Tint and contact your doctor as soon as possible (see under section 4: "Possible side effects").

ChloraPrep with Tint should only be applied to the skin gently. When the solution has been applied in an over-vigorous manner to very fragile or sensitive skin or after repeated use, rash, inflammation, itching, dry and/or flaky skin and pain may occur. At the first sign of any of these reactions, application of ChloraPrep with Tint should be stopped.

Prolonged skin contact should be avoided.
Soaked materials, such as drapes or gowns should be removed before use. The solution should not be allowed to pool.

The solution is flammable. Do not use ignition sources until the skin is completely dry**.**

Children
Use with care in newborn babies, especially those born prematurely. ChloraPrep with Tint may cause chemical skin burns.

Other medicines and ChloraPrep with Tint
Tell your doctor or nurse if you have recently had a vaccine or skin test injection (patch test used to test for allergies).

Pregnancy, breast-feeding and fertility
There are no studies with ChloraPrep with Tint in pregnant or lactating women.

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

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

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

Driving and using machines
ChloraPrep with Tint does not affect your driving or ability to use machines.

3. How to use ChloraPrep with Tint

The antiseptic solution within the ChloraPrep with Tint system is kept inside the plastic applicator. Your doctor or nurse will select the applicator size based on the procedure site and area to be covered. Your doctor or nurse will rub the sponge gently over your skin, covering the skin area that needs to be prepared. Depending on your medical procedure, more than one applicator may be used.

ChloraPrep with Tint is only used on the skin and each applicator is only used once.

If you have any further questions on the use of this product, ask your doctor or nurse.

4. Possible side effects

Like all medicines, ChloraPrep with Tint can cause side effects, although not everybody gets them.

If you experience any of the following reactions stop using ChloraPrep with Tint and get immediate medical help: swelling of the face, lips, tongue or throat; a red itchy skin rash; wheezing or difficulty breathing; feeling faint and dizzy; a strange metallic taste in the mouth; collapse. You may be having an allergic reaction.

If you develop a rash or your skin becomes itchy, painful, red, blistery, dry or inflamed where you have used the product as a skin wash, stop using ChloraPrep with Tint and talk to your doctor or pharmacist.

Very rarely (fewer than 1 in 10,000 people), allergic or irritated skin reactions to the ingredients in ChloraPrep with Tint (chlorhexidine gluconate, isopropyl alcohol and the tint Sunset Yellow E110) have been reported.

Other possible side effects, for which it is not known how often they occur, are: eye irritation, pain, corneal injury (injury to the surface of the eye), and permanent eye damage including permanent visual impairment (following accidental ocular exposure during head, face and neck surgical procedures) in patients under general anaesthesia (deep painless sleep), chemical burns and skin burns in newborns/infants.

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Ireland
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie

Malta
ADR Reporting, Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ChloraPrep with Tint

Flammable. This medicine 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. Do not use this medicine after the expiry date which is stated on the label or carton after EXP. The expiry date refers to the last day of that month.

Keep this medicine out of the sight and reach of children.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What ChloraPrep with Tint contains

- The active substances are chlorhexidine gluconate 20 mg/ml and isopropyl alcohol 0.70 ml/ml.
- The other ingredients are purified water and Sunset Yellow (E110).

What ChloraPrep with Tint looks like and contents of the pack

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.

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

Marketing Authorisation Holder and Manufacturer
The Marketing Authorisation holder of ChloraPrep with Tint is
Becton Dickinson France
11 Rue Aristide Bergès,
38800 Le Pont de Claix,
France
1800937570

The Manufacturer of ChloraPrep with Tint is
BD Infection Prevention BV
Erembodegem-Dorp 86
9320 Erembodegem
Belgium

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria - Chloraprep gefärbt
Belgium - Getinte ChloraPrep, ChloraPrep coloré, Chloraprep gefärbt
Finland - ChloraPrep värillinen
France - ChloraPrep coloré
Germany - Chloraprep gefärbt
Ireland - ChloraPrep with Tint
Italy - ChloraPrep con Colorante
Luxembourg - ChloraPrep coloré
Malta - ChloraPrep with Tint
Netherlands - Getinte ChloraPrep
Norway - Chloraprep med farge
Portugal - Chloraprep laranja
Sweden - Chloraprep färgad
UK - ChloraPrep with Tint

This leaflet was last revised in 06/2024

License Number:
PA2287/001/001
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The following information is intended for healthcare professionals only:

ChloraPrep with Tint 2% w/v / 70% v/v Cutaneous Solution

Chlorhexidine Gluconate / Isopropyl Alcohol

3 ml / 10.5 ml / 26 ml

Instructions for using ChloraPrep with Tint applicators:
For cutaneous use. For external use only.
- Remove the applicator from the wrapper and hold it with the sponge facing downward.
- Squeeze the applicator **once only**:
    - 26 ml squeeze lever on handle
    - other products, squeeze wings
- Do not repeatedly pinch or pump the wings in an attempt to accelerate the saturation of the foam.
- Gently press the sponge 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 26 ml applicator includes two swabs. Clean intact umbilicus with enclosed swabs when applicable. (Moisten swabs by pressing against solution-soaked sponge applicator.)
- Allow the covered area to air dry completely.

ChloraPrep with Tint can be left on the skin post procedure.

Maximum coverage areas:
- 3 ml 15 cm x 15 cm
- 10.5 ml 25 cm x 30 cm
- 26 ml 50 cm x 50 cm

Precautions for Use:
- Allow ChloraPrep with Tint to dry completely before starting any medical procedure. Do not use electrocautery procedures until the skin is completely dry. Do not use excessive quantities 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.
- Use with care in neonates, especially those born before 32 weeks of gestation and within the first 2 weeks of life. ChloraPrep with Tint may cause chemical skin burns.
- Do not use near mucous membranes, as it may cause irritation, pain and chemical burns. If it does get into the mucous membranes, it should be washed quickly with plenty of water.
- ChloraPrep with Tint must not come into contact with the eye due to the risk of visual damage. If it comes into contact with the eyes, wash out immediately and thoroughly with water. An ophthalmologist's advice should be sought.
- Do not use on open skin wounds, broken or damaged skin.
- ChloraPrep with Tint should not come into contact with neural tissues or the middle ear.
- Chlorhexidine is incompatible with soap and other anionic agents.
- 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.
- Do not apply the solution in an over vigorous manner to very fragile or sensitive skin. 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, stop application of ChloraPrep with Tint.
- Do not use in patients with known hypersensitivity to ChloraPrep solution or any of its components, especially in those with a history of possible chlorhexidine related allergic reactions. Chlorhexidine-containing products are known causes of anaphylactic reactions during anaesthesia. 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.

- Special precaution should be taken to avoid patient exposure to any other product containing chlorhexidine during the course of the treatment.

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. Discard the applicator after use as per clinical waste procedures.

Please refer to the Summary of Product Characteristics for ChloraPrep with Tint for further detailed information.

Storage Procedures
ChloraPrep with Tint is for single use only and is sterile until the packaging is opened. Do not use ChloraPrep with Tint after the expiry date stated on the label or carton. The expiry date refers to the last day of that month. This medicine does not require any special temperature storage conditions. Store in the original packaging.

Active Substances
The active substances in ChloraPrep with Tint are 2% w/v chlorhexidine gluconate and 70% v/v isopropyl alcohol. The inactive ingredients in ChloraPrep with Tint are purified water and Sunset Yellow (E110).

Marketing Authorisation Holder
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11 Rue Aristide Bergès,
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France