Package leaflet: Information for the user

ChloraPrep 2% w/v / 70% v/v
cutaneous solution

chlorhexidine gluconate /isopropyl alcohol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
This medicine should always be used exactly as described in this leaflet or as your doctor, pharmacist, or nurse have told you.
- Keep this leaflet. You may need to read it again.
- Ask your doctor, pharmacist or nurse if you need more information or advice.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What ChloraPrep is and what it is used for
2. What you need to know before you use ChloraPrep
3. How to use ChloraPrep
4. Possible side effects
5. How to store ChloraPrep
6. Contents of the pack and other information

1. What ChloraPrep is and what it is used for

ChloraPrep is a cutaneous solution of chlorhexidine gluconate and isopropyl alcohol 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.

2. What you need to know before you use ChloraPrep

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

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using ChloraPrep.

ChloraPrep is for external use only.
ChloraPrep should not be used:
- near delicate linings (mucous membranes), as it may cause irritation. If it does get onto the delicate linings of the body passages, it should be washed quickly with plenty of water.
- on open skin wounds and broken or damaged skin.
- 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 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 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 and contact your doctor as soon as possible (see under section 4: "Possible side effects").

ChloraPrep should only be applied to the skin gently. When the solution is 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, applications of ChloraPrep 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, naked flames or strong heat sources near the treated area until the skin is completely dry**.**

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

Other medicines and ChloraPrep
Tell your doctor, pharmacist 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 in pregnant or lactating women.

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

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

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

3. How to use ChloraPrep

The antiseptic solution within the ChloraPrep system is kept inside the plastic applicator. Your doctor, pharmacist or nurse will select the applicator size based on the procedure site and area of skin to be covered. Your doctor, pharmacist 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 is only used on the intact skin and each applicator is only used once.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following reactions stop using ChloraPrep 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 and talk to your doctor, pharmacist or nurse.

Very rarely (fewer than 1 in 10,000 people), allergic or irritated skin reactions to the ingredients in ChloraPrep (chlorhexidine gluconate and isopropyl alcohol) 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

United Kingdom
Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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

5. How to store ChloraPrep

Keep this medicine out of the sight and reach of children

This medicine does not require any special temperature storage conditions.

Store in the original package; applicator is sterile unless the seal is broken.

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

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 contains

- The active substances are chlorhexidine gluconate and isopropyl alcohol.

  1 mL solution contains 20 mg of chlorhexidine gluconate (20 mg/mL) and 0.70 mL of isopropyl alcohol (0.70 mL/mL).

  1 applicator with 1 mL solution contains 20 mg of chlorhexidine gluconate (20 mg/mL) and 0.70 mL of isopropyl alcohol (0.70 mL/mL).

1 applicator with 1.5 mL solution contains 30 mg of chlorhexidine gluconate (20 mg/mL) and 1.05 mL of isopropyl alcohol (0.70 mL/mL).

1 applicator with 3 mL solution contains 60 mg of chlorhexidine gluconate (20 mg/mL) and 2.10 mL of isopropyl alcohol (0.70 mL/mL).

1 applicator with 10.5 mL solution contains 210 mg of chlorhexidine gluconate (20 mg/mL) and 7.35 mL of isopropyl alcohol (0.70 mL/mL).

1 applicator with 26 mL solution contains 520 mg of chlorhexidine gluconate (20 mg/mL) and 18.20 mL of isopropyl alcohol (0.70 mL/mL).

- The other ingredient is purified water.

What ChloraPrep looks like and contents of the pack

The Frepp 1.5 mL applicator consists of a latex-free rectangular foam sponge attached to a plastic barrel which holds a glass ampoule containing the antiseptic solution. The 1 mL, 1.5 mL, 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 film.

The packaging consists of a lidding material sealed to a polymeric film creating a “pouch-like" packet surrounding the applicator.

Pack Sizes:

Multipacks containing 60 applicators each containing 1 mL cutaneous solution.

Multipacks containing 20 applicators each containing 1.5 mL (Frepp) cutaneous solution.

1 applicator containing 1.5 mL cutaneous solution.

Multipacks containing 25 applicators each containing 1.5 mL cutaneous solution.

1 applicator containing 3 mL cutaneous solution.

Multipacks containing 25 applicators each containing 3 mL cutaneous solution.

1 applicator containing 10.5 mL cutaneous solution.

Multipacks containing 25 applicators each containing 10.5 mL cutaneous solution.

1 applicator containing 26 mL cutaneous solution.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer
The Marketing Authorisation holder of ChloraPrep is
Becton Dickinson UK Ltd
1030 Eskdale Road, Winnersh,
Wokingham, RG41 5TS,
United Kingdom

Customer contact for adverse events or medical information inquiries: +44 800 043 7546

The Manufacturer of ChloraPrep is
Insight Health Limited
Unit A Bridgefields,
Welwyn Garden City, Hertfordshire AL7 1RX
United Kingdom

BD Infection Prevention BV
Erembodegem-Dorp 86
9320 Erembodegem
Belgium

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom under the following names:

Austria - ChloraPrep 20 mg/ml + 0,7 ml/ml Lösung zur Anwendung auf der Haut
Belgium - ChloraPrep à 2 % p/v / 70 % v/v solution pour application cutanée Finland - ChloraPrep 20 mg/ml / 0,70 ml/ml liuos iholle
France – CHLORAPREP, solution pour application cutanée
Germany - ChloraPrep 2 % w/v / 70 % v/v Lösung zur Anwendung auf der Haut
Ireland - ChloraPrep 2% w/v / 70% v/v cutaneous solution
Italy - ChloraPrep 2% p/v / 70% v/v soluzione cutanea
Luxembourg - ChloraPrep à 2 % p/v / 70 % v/v solution pour application cutanée
Malta - ChloraPrep 2% w/v / 70% v/v cutaneous solution
Netherlands - ChloraPrep 2% w/v / 70% v/v oplossing voor cutaan gebruik
Norway - Chloraprep 20 mg/ml + 0,70 ml/ml liniment, oppløsning
Portugal - Chloraprep 20 mg/ml + 550 mg/ml solução cutânea
Sweden - Chloraprep 20 mg/ml + 0,70 ml/ml kutan lösning
UK – ChloraPrep 2% w/v / 70% v/v cutaneous solution

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Licence Number:
PL 05920/0002
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The following information is intended for healthcare professionals only:

ChloraPrep 2% w/v / 70% v/v
cutaneous solution

chlorhexidine gluconate /isopropyl alcohol

Instructions for using ChloraPrep 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.

- Allow the covered area to air dry completely.

ChloraPrep can be left on the skin post procedure.

Maximum coverage areas:

- 1 mL	8 cm x 10 cm
- 1.5 mL (Frepp)	10 cm x 13 cm
- 1.5 mL	10 cm x 13 cm
- 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 to dry completely before starting any medical procedure. Do not use ignition sources, naked flames or strong heat sources near the treated area until the skin is completely dry. Do not use excessive quantities of ChloraPrep 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 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 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 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.
- Do not use in patients with known hypersensitivity to the active substances or to any of the excipients, 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 product is for single use.

The solution is flammable. Avoid exposure of the container and contents to naked flames during use, storage or disposal. Discard the applicator after use as per clinical waste procedures.

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

Storage Procedures
ChloraPrep is for single use only and is sterile until the packaging is opened. Do not use ChloraPrep 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 package.

Active Substances
The active substances in ChloraPrep are 2% w/v chlorhexidine gluconate and 70% v/v isopropyl alcohol. The inactive ingredient in ChloraPrep is purified water.

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