

Package leaflet: Information for the user

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

Chlorhexidine Gluconate / Isopropyl Alcohol

**1 ml / Frepp 1.5 ml / 1.5 ml /
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 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 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.

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 (see Section 6).

Warnings and precautions

ChloraPrep is for external use only.

ChloraPrep should not be used:

- near eyes or delicate linings (mucous membranes), as it may cause irritation. If it does get into the eye or 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 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 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, 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 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 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 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 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 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, blistering, dry or inflamed where you have used the product as a skin wash, stop using ChloroPrep 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 ChloroPrep (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, impaired vision, chemical burns, eye injury, 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 ChloroPrep

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 ChloroPrep contains

- The active substances are chlorhexidine gluconate 20 mg/ml and isopropyl alcohol 0.70 ml/ml.
- The other ingredient is purified water.

What ChloroPrep 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 transparent film.

Pack Size:

1 ml: 60 applicators
1.5 ml Frepp: 20 applicators
1.5 ml: 1 applicator or 25 applicators
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 is

Becton Dickinson France

11 Rue Aristide Bergès,

38800 Le Pont de Claix,

France

IE : 1800937570

MT: 80065065

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

Austria - ChloraPrep

Belgium - ChloraPrep

Finland - ChloraPrep

France - ChloraPrep

Germany - ChloraPrep

Ireland - ChloraPrep

Italy - ChloraPrep

Luxembourg - ChloraPrep

Malta - ChloraPrep

Netherlands - ChloraPrep

Norway - Chloraprep

Portugal - Chloraprep

Sweden - Chloraprep

UK - ChloraPrep

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The following information is intended for healthcare professionals only:

ChloroPrep 2% w/v / 70% v/v Cutaneous Solution

Chlorhexidine Gluconate / Isopropyl Alcohol

**1 ml / Frepp 1.5 ml / 1.5 ml /
3 ml / 10.5 ml / 26 ml**

Instructions for using ChloroPrep 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.

ChloroPrep can be left on the skin post procedure.

Maximum coverage areas:

- | | |
|------------------|---------------|
| - 1 ml | 8 cm x 10 cm |
| - Frepp (1.5 ml) | 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 ChloroPrep 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. ChloroPrep may cause chemical skin burns.
- Do not use near eyes or mucous membranes, as it may cause irritation, eye irritation, pain, impaired vision, chemical burns and eye injury. If it does get into the eye or the mucous membranes, it should be washed quickly with plenty of water.
- Do not use on open skin wounds, broken or damaged skin.
- ChloroPrep 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 ChloroPrep.
- Do not use in patients with known hypersensitivity to ChloroPrep 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 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 packaging.

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.

Marketing Authorisation Holder

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