

Package leaflet: Information for the user

ChloraPrep 2% w/v / 70% v/v impregnated cutaneous swab

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, which is presented as a plastic stick with a foam pad that is impregnated with a fast-acting antiseptic solution on one end. The product is used to disinfect the skin and help prevent infections before invasive medical procedures.

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).
- in the ear canal as the solution may damage your hearing.

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.
- 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.

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 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 is kept inside an aluminium pouch that also contains the swab(s). Your doctor, pharmacist or nurse will select the pouch size and the number of ChloraPrep swabs needed, based on the procedure site and area of skin to be covered. Your doctor, pharmacist or nurse will rub the foam pad gently over your skin, covering the skin area that needs to be prepared. Depending on your medical procedure, more than one pouch may be used.

Other ChloraPrep applicators may be more suitable, depending on the medical procedure being undertaken.

ChloraPrep is only used on the intact skin and each swab 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 the product application should be stopped: 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, 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, chemical burns, 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) 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 HPRA Pharmacovigilance, Website: www.hpra.ie.

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; ChloraPrep 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. Each single swab pouch of 1.75 mL solution contains 35 mg of chlorhexidine gluconate (20 mg/mL) and 1.23 mL of isopropyl alcohol (0.70 mL/mL). Each three-swab pouch of 5.25 mL solution contains 105 mg of chlorhexidine gluconate (20 mg/mL) and 3.7 mL of isopropyl alcohol (0.70 mL/mL).
- The other ingredient is purified water.

What ChloroPrep looks like and contents of the pack

ChloroPrep swabs consist of a plastic stick connected to an impregnated foam tip, which are sealed in a plastic foil pouch containing the antiseptic solution.

A pouch can contain either one or three swabs.

Pack Sizes:

1.75 mL (Single swab):	Carton of 48 pouches (total: 48 swabs)
5.25 mL (Triple swabs):	Carton of 40 pouches each containing 3 swabs (total: 120 swabs)

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation holder of ChloroPrep is

Becton Dickinson France

11 Rue Aristide Bergès,

38800 Le Pont de Claix,

France

Customer contact for adverse events or medical information inquiries: 1800 937 570

The Manufacturer of ChloroPrep is

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:

Finland: ChloroPrep 20 mg/mL + 0,70 mL/mL kyllästetty lääketuppo iholle

France : CHLORAPREP, tampon cutané imprégné en applicateur

Germany: ChloroPrep 2 % w/v / 70 % v/v Imprägnierter Tupfer zur Anwendung auf der Haut

Ireland: ChloroPrep 2% w/v / 70% v/v impregnated cutaneous swab

Italy: ChloroPrep 2% p/v / 70% v/v tampone cutaneo medicato

Norway: Chloraprep 20 mg/mL + 0,70 mL/mL impregnert vattpinne til bruk på hud

Sweden: Chloraprep 20 mg/mL + 0,70 mL/mL impregnerad kutan svabb

United Kingdom: ChloroPrep 2% w/v / 70% v/v impregnated cutaneous swab

This leaflet was last revised in **MM/YYYY**.

Licence Number:

PA2287/001/003

The following information is intended for healthcare professionals only:

ChloroPrep 2% w/v / 70% v/v impregnated cutaneous swab

chlorhexidine gluconate / isopropyl alcohol

Instructions for using ChloroPrep:

For cutaneous use. For external use only. Choose the appropriate ChloroPrep presentation based on the invasive procedure being undertaken and the size of the area to be prepared in order to avoid administering excess solution and the risk of product pooling.

Other ChloroPrep applicators may be more suitable depending on the medical procedure being undertaken.

- Only the inside of the pouch is sterile. In order to preserve sterility, the pouch should be opened carefully, and the foam pad should not be allowed to touch any non-sterile surface.
- Tear the pouch at its side notch to reveal the swab handle(s). Do not touch the swab foam pad.
- Place the foam pad flat-side down on the treatment area of the patient's skin.
- Apply the solution for 30 seconds using a gentle back and forth motion.
- Allow the covered area to air dry completely.
- For triple swabs, use the swabs sequentially for a total of 30 seconds.

ChloroPrep solution can be left on the skin post procedure.

Maximum coverage areas:

- Single swab (1.75 mL) 6 cm x 7 cm
- Triple swabs (5.25mL) 10 cm x 16 cm

Precautions for Use:

- Allow ChloroPrep solution to dry completely on the skin 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 ChloroPrep 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 mucous membranes, as it may cause irritation, pain, impaired vision and chemical burns. If it does get into the mucous membranes, it should be washed quickly with plenty of water.
- ChloroPrep 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.
- ChloroPrep should not come into contact with neural tissues. To prevent exposure of the middle ear to ChloroPrep via a perforation of the eardrum, the use of ChloroPrep in the ear canal is contraindicated.
- 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 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 swab after use as per clinical waste procedures.

Please refer to the Summary of Product Characteristics of 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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