PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed without a doctor's prescription

ChloraPrep

Composition:
Active ingredients
Chlorhexidine gluconate 20 mg/ml and isopropyl alcohol 0.70 ml/ml.
Inactive ingredients and allergens - see section 6 "Further information".

Read all of this leaflet carefully before you start taking this medicine.
This leaflet contains concise information about the medicine. If you have further questions, consult the doctor or pharmacist.

Use this medicine in accordance with the instructions in the dosage section in this leaflet. Consult the pharmacist if you need further information. Refer to the doctor if signs of the illness worsen or do not improve.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicinal product is to be used for disinfection of the skin prior to invasive medical procedures.
Therapeutic group: Chlorhexidine, combinations.

2. BEFORE USING THE MEDICINE

Do not use the medicine 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).

Special warnings regarding use of the medicine
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: "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
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
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 has no or negligible influence on the ability to drive and operate machinery.

3. HOW SHOULD THE MEDICINE BE USED?
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the product.

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.

Do not exceed the recommended dose.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take a medicine. Wear glasses if you need them.

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

4. SIDE EFFECTS

As with any medicine, use of Chloraprep may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of 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 or pharmacist.

Very rare side effects - effects that occur in less than one user in 10,000:
Allergic or irritated skin reactions to the ingredients in ChloraPrep (chlorhexidine gluconate and isopropyl alcohol) have been reported.
Side effects with unknown frequency (for which frequency has not yet been determined):
Eye irritation, pain, impaired vision, chemical burns, eye injury, skin burns in newborns/ infants.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

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

Flammable.
This medicine does not require any special storage conditions. It is recommended to store at room temperature.
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 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. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains:

Purified water.

What the medicine looks like and the contents of the package:
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.

Registration Holder and address:
Becton Dickinson (BD) Israel Ltd. 2 Harduf Hanehalim street, Caesarea, Israel
Manufacturer and address:
CareFusion 213 LLC. 1550 Northwestern Drive – El Paso, Texas 79912 – USA

Approved in March 2023

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Chloraprep: 172-49-36418-00

The following information is intended for healthcare professionals only:

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:**
- In the 26 ml volume product squeeze lever on handle
- In 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 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 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 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.
- 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 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 for further detailed information.