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
2. What you need to know before you use ChloraPrep with Tint
3. How to use ChloraPrep with Tint
4. Possible side effects
5. How to store ChloraPrep with Tint
6. Contents of the pack and other information

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. 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 4).

Warning and precautions
ChloraPrep with Tint is for external use only. ChloraPrep with Tint 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 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.

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 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 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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