ChloraPrep® with Tint 2% w/v / 70% v/v
Cutaneous Solution
Chlorhexidine Gluconate 20mg/ml / Isopropyl Alcohol 0.70ml/ml
3-ml / 10.5-ml / 26-ml

Read all of this leaflet carefully 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 notice any side effects not listed in this leaflet, please tell your doctor or nurse.

1. What is ChloraPrep with Tint and why is it used?
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 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. ChloraPrep with Tint contains a tint to colour the skin, which plays no role in the antiseptic properties of the solution.

2. BEFORE CHLORAPREP WITH TINT IS USED
Do not use ChloraPrep with Tint:
- if you are allergic (hypersensitive) to chlorhexidine gluconate, isopropyl alcohol, or Sunset Yellow (E110). (See Section 6 “Further information” for a full list of ingredients).

Take special care with ChloraPrep with Tint.
ChloraPrep with Tint is for external use only.
- ChloraPrep with Tint should not be used:
  - on children less than 2 months old.
  - near eyes or delicate linings (mucus 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 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 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 with ignition sources until dry.

Using other medicines
Tell your doctor or nurse if you have recently had a vaccine or skin test injection (patch test used to test for allergies).

Pregnancy and breast-feeding
If you are pregnant, planning to become pregnant or breast-feeding, ChloraPrep with Tint can still be used. You can talk about this more with your doctor or nurse.

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

3. HOW CHLORAPREP WITH TINT WILL BE USED
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.

4. POSSIBLE SIDE EFFECTS
Like all medicines, ChloraPrep with Tint can cause side effects, although not everybody gets them.
Very rarely (fewer than 1 in 10,000 people), allergic or irritated skin reactions to the ingredients in ChloraPrep with Tint (chlorhexidine gluconate, isopropyl alcohol and the tint Sunset Yellow E110) have been reported.
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.
If the side effect gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse immediately.

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any side effects not listed in this leaflet. You can also report side effects directly via:
See other side for further instructions.
- 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.

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 its contents to naked flames during use, storage and disposal. Discard the applicator after use 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. Do not store above 25°C. Avoid freezing. 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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United Kingdom

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What Chloraprep looks like and contents of the pack

Chloraprep with Tint is a sterile alcoholic antiseptic solution containing chlorhexidine gluconate and isopropyl alcohol in an applicator. The applicators consist of a latex-free sponge attached to a plastic handle/barrel which holds a latex-free dyed pledget and glass ampoule containing the antiseptic solution. The 3ml and 10.5ml applicators each have a single glass ampoule within the plastic barrel. The 26ml applicator holds two 13ml glass ampoules. The sterile applicators are individually packaged in an ethyl vinyl acetate film.

Pack Size:

- 3ml: 25 applicators
- 10.5ml: 1 applicator or 25 applicators
- 26ml: 1 applicator

Not all pack sizes may be marketed.

- Medicines should not be discarded via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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

5. HOW TO STORE CHLORAPREP WITH TINT

Flammable. Do not store Chloraprep with Tint above 25 ºC.

Store in the original packaging; applicator is sterile until the seal is broken.

Do not expose the container or its contents to naked flames during use or storage. Do not use past the expiry date.

Keep out of the reach and sight of children.

6. FURTHER INFORMATION

What Chloraprep contains

The active substances are chlorhexidine gluconate 20mg/ml and isopropyl alcohol 0.70ml/ml. The other ingredients are purified water and Sunset Yellow (E110).

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

- Austria - Chloraprep gefärbt
- Belgium – Gretine Chloraprep, Chloraprep Colouré, Chloraprep gefärbt
- Finland - Chloraprep värisillinen
- France - Chloraprep Coloré
- Germany - Chloraprep gefärbt
- Greece - SteelPrep
- Ireland – Chloraprep with Tint
- Italy – Chloraprep con Colorante
- Luxembourg - Chloraprep Colouré
- Malta - Chloraprep with Tint
- Netherlands - Gretine Chloraprep
- Norway – Chloraprep med farge
- Portugal – Chloraprep laranja
- Sweden - Chloraprep färgad
- United Kingdom - Chloraprep with Tint

Is this leaflet difficult to read? You can ask for a copy either in large print, Braille, on CD or tape cassette by calling the MA Holder at +44 (0)800 043 7546.

This leaflet was last revised in 05/2014.

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License Numbers:

UK: PL 31760/0001
IE: PA 1435/11
MT: MA 700/00101

Artwork 6-775000EU 052014