

## Package Leaflet: Information for the patient

### **Soluprep 2% w/v / 70% v/v cutaneous solution** **Soluprep with tint 2% w/v / 70% v/v cutaneous solution**

Chlorhexidine Gluconate / Isopropyl Alcohol

Colourless solution: 10.5 mL in applicator

Green tinted solution: 10.5 mL/26 mL in applicator

**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 <Invented name> is and what it is used for
2. What you need to know before <Invented name> is used
3. How <Invented name> is used
4. Possible side effects
5. How to store <Invented name>
6. Contents of the pack and other information

#### **1. What <Invented name> is and what it is used for**

<Invented name> is a sterile antiseptic solution of chlorhexidine gluconate 20mg/mL and isopropyl alcohol 0.70mL/mL in an applicator with a sponge tip on one end. The applicator contains a fast acting antiseptic solution, which is used in subjects aged 1 year and above to disinfect the skin before invasive medical procedures (such as insertion of catheters, minor and major surgery) to help reduce bacteria that potentially can cause skin infection.

<Invented name> tinted solution contains a tint to colour the skin, it plays no role in the antiseptic properties of the solution.

#### **2. What you need to know before <Invented name> is used**

**<Invented name> must not be used:**

- if you are allergic to chlorhexidine gluconate, isopropyl alcohol or any of the other ingredients of this medicine (listed in section 6).

### **Warnings and precautions**

<Invented name> is for external use only on intact skin.

The solution is flammable. Do not use electrocautery procedures (i.e. surgical procedures where a surgeon or doctor used electricity to heat tissue to prevent or stop bleeding or remove abnormal tissue growth) or other ignition sources until the skin is completely dry.

<Invented name> 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 into contact with the eye during surgical procedures, in patients under general anaesthesia (deep painless sleep).

<Invented name> should not be used:

- In the ears (including the middle ear, part of the ear that is inside the body) or on delicate linings (mucous membranes), as the solution may cause serious or permanent injury if it comes into contact with these areas. If it does get in contact with these areas, it should be washed quickly with plenty of cold water and a doctor should be contacted;
- on open skin wounds or broken or damaged skin;
- as general skin cleanser;
- for lumbar puncture (the procedure of taking fluid from the spine in the lower back through a hollow needle) or in contact with neural tissue (for example brain and spinal cord tissue);

Avoid prolonged skin contact. If signs of local skin reaction appear, the use of <invented name> should be stopped.

### **Children**

<Invented name> may be used in all age groups and patient populations. However, <invented name> is not recommended in children less than 1 year old. <Invented name> may cause irritation or chemical skin burns in newborn babies, especially those born prematurely.

### **Other medicines and <Invented name>**

Tell your doctor or nurse if you are using, have recently used or might use any other medicines.

### **Pregnancy and breast-feeding**

There are no studies with this product in pregnant or lactating women.

#### **Pregnancy**

<Invented name> may be used during pregnancy.

#### **Breast-feeding**

<Invented name> may be used during breast-feeding.

### **Driving and using machines**

<Invented name> does not affect your driving or ability to use machines.

## **3. How <Invented name> is used**

The antiseptic solution is in the applicator. The 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 solution over your skin, covering the skin area that needs to be prepared.

<Invented name> is only used on the skin and each applicator is only used once.

If you have any further questions on the use of this medicine, ask your doctor 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 tell your health care provider and get medical help immediately as you may be having an allergic reaction:

- swelling of the face, lips, tongue or throat
- a red itchy skin rash
- wheezing or difficulty breathing
- feeling faint or dizzy

The frequency of allergic reactions are not known.

Other side effects that may occur:

Common (may affect up to 1 in 10 people)

- Reactions at the application site: rash, reddening of the skin, small fluid-filled bumps, pain and itching at the application site;

Very rare (may affect up to 1 in 10,000 people)

- allergic or irritation skin reactions including rash, reddening of the skin, itching and application site blisters;
- local symptoms such as skin burning sensation, pain and inflammation;

Frequency unknown

- dermatitis (skin becomes red, swollen and sore), eczema (patches of rough, dry inflamed skin), urticaria (hives), chemical burns in neonates.
- 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 procedure) in patients under general anaesthesia (deep painless sleep).

#### 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 the national reporting system listed in Appendix V.\*

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

#### 5. How to store <Invented name>

Keep this medicine out of the sight and reach of children.

Do not store above 30°C. Do not refrigerate or freeze.

Flammable. Keep away from fire and naked flame during use, storage and disposal. Store in the original package.

Do not use this medicine after the expiry date which is stated on the pouch and applicator label.

<Invented name> is for single use only and is sterile until the packaging is opened. Do not use the medicine if the package has been damaged.

Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment.

#### 6. Contents of the pack and other information

**What <Invented name> contains**

- The active substances are chlorhexidine gluconate 20 mg/ml/ isopropyl alcohol 0.70 ml/ml
- The other ingredients are:  
Tributyl acetylcitrate, Purified water, Trisodium Hydroxyethyl Ethylenediamine Triacetic Acid (HEDTA).
- The other ingredients are:  
Tributyl acetylcitrate, Purified water, E102 Tartrazine, E133 Brilliant Blue, Trisodium Hydroxyethyl Ethylenediamine Triacetic Acid (HEDTA).

**What <Invented name> looks like and contents of the pack**

<Invented name> is a colourless solution. <Invented name> is a green tinted solution. It is provided in an applicator which consists of foam sponge attached to a plastic barrel which holds a glass ampoule containing the sterile antiseptic cutaneous solution. The container closure system is not made with natural rubber latex. Two cotton-tipped swabs are provided with each 26-mL pack. The applicators are sterile and individually packaged.

10.5 mL green tinted solution: 50 applicators

10.5 mL colourless solution: 50 applicators

26 mL green tinted solution: 20 applicators

**Marketing Authorisation Holder and Manufacturer****Marketing Authorisation Holder**

<[To be completed nationally]>

**Manufacturer (EU Importer)**

<[To be completed nationally]>

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

Austria: Soluprep steril

Belgium: Chlorhexidine gluconate / isopropyl alcohol 3M Deutschland GmbH

France: Digluconate de chlorhexidine / alcool isopropylique 3M Deutschland GmbH

Germany: Soluprep steril

Ireland: Soluprep

Netherlands: Soluprep

Norway: Chlorhexidine gluconate / isopropyl alcohol 3M

Sweden: Soluprep

UK: Soluprep

**This leaflet was last revised in:**

2025-08-26

**The following information is intended for healthcare professionals only:**

**Soluprep 2% w/v / 70% v/v cutaneous solution**  
**Soluprep with tint 2% w/v / 70% v/v cutaneous solution**  
**Chlorhexidine Gluconate / Isopropyl Alcohol**

**Instructions for using <Invented name> applicators:**

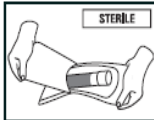
For cutaneous use. For external and single use only.

The volume of solution (i.e. applicator size) will dependent upon type of invasive medical procedure.

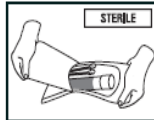
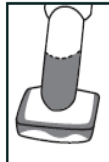
As this product does not have presentations of smaller volumes, prescribers should use alternate products for disinfection of skin prior to simple invasive procedures that require small volume.

| Solution Volume (mL) | Applicator | Maximum Coverage Area (cm x cm)       |
|----------------------|------------|---------------------------------------|
| 10.5                 | Tint       | 34 cm x 34 cm (1156 cm <sup>2</sup> ) |
| 10.5                 | Colourless |                                       |
| 26                   | Tint       | 50 cm x 50 cm (2500 cm <sup>2</sup> ) |

**10.5mL**

- Remove the applicator from the pouch without touching the sponge. 
- To activate the applicator:
  - Hold the applicator with the sponge facing **parallel** to the floor.
  - Place your thumb on the lever; press **firmly** to 'snap' the lever.
- Wait for the solution to flow into the applicator sponge. 
- Completely wet the treatment area with antiseptic using **repeated back-and-forth strokes**:
  - Dry surgical sites (e.g., abdomen or arm): apply antiseptic for 30 seconds.
  - Moist surgical sites (e.g., inguinal fold): apply antiseptic for 2 minutes.
- Wait until solution is completely dry (minimum of 3 minutes on hairless skin) to reduce risk of fire. 

**26mL**

- Remove the applicator from the pouch without touching the sponge. Two cotton-tipped swabs are provided and can be used to clean the umbilicus when applicable. 
- To activate the applicator:
  - Hold the applicator with the sponge facing **parallel** to the floor.
  - With the palm of your hand, press down **firmly** on the end cap until it 'clicks'
- Wait for the solution to flow into the applicator sponge. 
- Completely wet the treatment area with antiseptic using **repeated back-and-forth strokes**:
  - Dry surgical sites (e.g., abdomen or arm): apply antiseptic for 30 seconds.
  - Moist surgical sites (e.g., inguinal fold): apply antiseptic for 2 minutes.
- Wait until solution is completely dry (minimum of 3 minutes on hairless skin) to reduce risk of fire. 

**Precautions for Use:**

- <Invented name> must not come into contact with the eye. Serious cases of persistent corneal injury, potentially requiring corneal transplant, were reported following accidental ocular exposure to chlorhexidine containing medicinal products despite taking eye protective measures due to migration of solution beyond the intended surgical preparation area. Extreme care must be taken during application to ensure that <invented name> does

not migrate beyond its intended application into the eyes. Particular care should be taken in anaesthetised patients, who are unable to immediately report ocular exposure.

If <invented name> comes into contact with the eyes, wash out promptly and thoroughly with water. An ophthalmologist's advice should be sought.

- Keep out of ears and mouth. The solution may cause serious or permanent injury if it comes into contact with these areas. If contact occurs, rinse immediately and thoroughly with cold water and contact a doctor.
- <Invented name> may be used in all age groups and patient populations. However, <invented name> is not recommended in children less than 1 year old. <Invented name> may cause chemical skin burns in newborn babies, especially those born prematurely.
- Avoid getting solution into hair. Wet hair is flammable. Hair may take up to 1 hour to dry.
- Chlorhexidine is incompatible with soap and other anionic agents.
- Prolonged skin contact with alcohol containing solutions should be avoided. At the first sign of local skin reaction the use of <invented name> should be discontinued.

While waiting for solution to completely dry:

- Do not drape or use ignition source (e.g., electrocautery, laser).
- 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.
- Remove wet materials from prep area. Replace if necessary.

After solution is completely dry:

- To reduce risk of fire, begin draping and/or using cautery only after solution is completely dry and all wet materials are removed.
- If incise drapes are used, apply directly to dry prep.
- Apply dressing following standard practices.

It is recommended that the antiseptic remain on the skin after the procedure for continued protection. The antiseptic will gradually wear away. If early removal is desired, use soap and water or isopropyl alcohol.