

The ChloraPrep range

- Different size applicators for different procedures
- The optimal amount of sterile solution for a given area of skin
- Flow control helps prevent pooling and promote even distribution

1.5ml clear	3ml Tint and Clear	10.5ml Tint and Clear	26ml Tint and Clear	FREPP 1.5ml	SEPP .67ml
Coverage area 10 cm x 13 cm	Coverage area 15 cm x 15 cm	Coverage area 25 cm x 30 cm	Coverage area 50 cm x 50 cm	Coverage area 10 cm x 13 cm	Coverage area 5 cm x 8 cm

Prescribing Information:

ChloroPrep® & ChloroPrep with Tint 2% chlorhexidine gluconate w/v / 70% isopropyl alcohol v/v cutaneous solution. Refer to the Summary of Product Characteristics before prescribing. **Presentation:** ChloroPrep – each applicator contains 0.67 mL, 1.5 mL, 3 mL, 10.5 mL or 26 mL of 20 mg/mL chlorhexidine & 0.70 mL/mL isopropyl alcohol; ChloroPrep with Tint – each applicator contains 3 mL, 10.5 mL or 26 mL of 20 mg/mL chlorhexidine & 0.70 mL/mL isopropyl alcohol. **Indication:** Disinfection of skin prior to invasive medical procedures. **Dosage & administration:** Applicator volume dependent on invasive procedure being undertaken. May be used for all age groups and patient populations. Use with care in newborn babies and those born prematurely. Applicator squeezed to break ampoule and release antiseptic solution onto sponge. Solution applied by gently pressing sponge against skin and moving back and forth for 30 seconds. The area covered should be allowed to air dry. **Contraindications:** Patients with known hypersensitivity to ChloroPrep or ChloroPrep with Tint or any of its components, especially those with a history of possible Chlorhexidine-related allergic reactions. **Warnings and precautions:** Solution is flammable. Do not use with ignition sources until dry. Do not use in excessive quantities, allow to pool in patient skin folds or drip on materials in contact with patient skin. Remove any soaked materials before proceeding with the intervention. Ensure no excess product is present prior to application of occlusive dressing. For external use only on intact skin, do not use on open skin wounds or broken or damaged skin. Over-vigorous use on fragile or sensitive skin or repeated use may lead to local skin reactions. Avoid prolonged skin contact. Avoid contact with eyes, mucous membranes, middle ear and neural tissue. Chlorhexidine may induce hypersensitivity, including generalised allergic reactions and anaphylactic shock. May cause chemical burns in neonates, with a higher risk in preterm infants and within the first 2 weeks of life. **Pregnancy & lactation:** Although no studies have been conducted, no effects are anticipated as systemic exposure is negligible. **Undesirable effects:** Very rare; allergic or irritation skin reactions to chlorhexidine, isopropyl alcohol or sunset yellow (E110, present in ChloroPrep with Tint only), including erythema, rash, pruritus and blisters or application site vesicles, other local symptoms have included skin burning sensation, pain and inflammation. Frequency not known; hypersensitivity including anaphylactic shock, dermatitis, eczema, urticaria, chemical burns in neonates. Discontinue use at the first sign of local skin reaction. **Per applicator costs (ex VAT):** ChloroPrep: 0.67ml (SEPP) - UK £0.30, Ireland €0.39; 1.5ml (FREPP) - UK £0.55, Ireland €0.64; 1.5ml – UK £0.78, Ireland €0.94; 3ml; 3ml – UK £0.85, Ireland €1.06; 10.5ml - UK £2.92, Ireland €3.79; 26ml – UK £6.50, Ireland €7.96. ChloroPrep with Tint: 3ml – UK £0.89, Ireland €1.09; 10.5ml – UK £3.07, Ireland €3.88; 26ml - UK £6.83, Ireland €8.19. **Legal category:** GSL **Marketing**

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Authorisation Numbers: ChloroPrep, (UK: PL31760/0004; Ireland: PA1435/001/002) & ChloroPrep with Tint, (UK: PL31760-0001; Ireland: PA1435/001/001). **Marketing Authorisation Holder:** CareFusion UK 244 Ltd, The Crescent, Jays Close, Basingstoke, Hampshire, RG22 4BS. **Date of Preparation:** December 2016.

Reporting suspected adverse reactions is important to monitor the benefit/risk balance of the medicinal product. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to CareFusion Freephone number. For UK: 0800 0437 546 or email CareFusionGB@professionalinformation.co.uk. For Ireland: 01404 8383 or email CareFusionIE@professionalinformation.co.uk.

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References:

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5. Medicines and Healthcare Products Regulatory Authority, Public Assessment Report 2012; UK/H/1305/002/DC
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ISKUS HEALTH
IMPROVING PATIENT OUTCOMES



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Setting a new standard in operating procedures

Compared with povidone iodine

ChloroPrep is recommended by, or complies with, the infection control guidelines of many organisations, including:

2002

American Academy of Pediatrics
Centers for Disease Control and Prevention

2003

National Institute for Health and Clinical Excellence
Society for Interventional Radiology

2006

Health Protection Agency Rapid Review Panel (Recommendation 1)
National Kidney Foundation

2007

epic2Guidelines

2010

The World Health Organization
A Strategy for the Control of Antimicrobial Resistance in Ireland (SARI)

2011

Department of Health Saving Lives Delivery Programme: Hills
Public Health England's Rapid Review Panel (Recommendation 1)
Institute for Healthcare Improvement

2012

Scottish Intensive Care Society Audit Group (SICSAG)
Health Protection Scotland
Royal College of Nursing
Royal College of Surgeons in Ireland / Royal College of Physicians of Ireland

2014

Association of Breast Surgery / British Association of
Reconstructive and Aesthetic Surgeons
epic3 Guidelines

Not all 2% CHG / 70% IPA solutions are the same

Only ChloraPrep™ is licensed

The MHRA requires products used for cutaneous antisepsis prior to invasive procedures to have a licence²

Companies or manufacturers selling CHG products without marketing authorisation are in breach of regulatory requirements³

ChlorPrep is the only 2% CHG / 70% IPA system licensed by the FDA and MHRA^{4,5}

Because of this, ChlorPrep trial data have not only been scrutinised, but the system has a well-defined product safety monitoring and response process

Only ChlorPrep is sterile for each patient use

Despite their pharmacologic activity, bulk antiseptic products can be contaminated with microbial organisms posing a significant threat to patient health⁶

There have been published reports linking outbreaks of infection to antiseptic products from all commonly-used antiseptic categories, including alcohol, iodophors and CHG⁶

Topical antiseptics should be considered a source of postoperative or postinjection infection⁷

Only ChlorPrep has an applicator designed for purpose

The method of application plays an important role in skin antisepsis⁸

Good antisepsis is more likely to occur with convenient products – as offered by the selection of single-use applicators⁵

While concentric prepping ensures the skin has been painted with a disinfecting solution, moving gently back and forth over the same area will remove the greater part of the bacterial load that resides in the stratum corneum⁹

A back and forth prep was used in all the phase III efficacy studies of ChlorPrep applicators¹⁰

ONLY 2% CHG / 70% IPA
IN THE CHLORAPREP
APPLICATOR HAS BEEN
PROVEN TO CUT SSIs

BY 41%^{*1}

1 STERILE 2% CHG / 70% IPA SOLUTION

Manufactured sterile from the inside out, the solution, (terminally sterilised post ampoulsation), is maintained in a glass ampoule prior to activation

Sterile dye is introduced upon activation

2 STERILE APPLICATOR

Designed to facilitate proven back and forth application technique, whilst maintaining user asepsis (ANTT[®])

With everything contained in a single unit, there is only one thing to open and throw away helping protect the sterile operating field

3 STERILE SPONGE

Polyester urethane sponge does not chemically interact with the solution

Designed for comfort, with minimal dermal abrasion

Helping to regulate flow to prevent splashing or pooling during application which mitigates the risk of chemical and thermal burns



● MITIGATING FIRE RISKS

The most common source of surgical fire is from the presence of flammable skin antiseptic¹¹

“Alcohol-based skin preparation solutions should be applied using a purpose-built applicator that...minimizes pooling and excess application of solution”¹¹

Annals of The Royal College of Surgeons of England, 2012

On the basis of evidence, Public Health England’s Rapid Review Panel gave ChlorPrep its highest recommendation (Recommendation 1)¹²

Product Code	Description
270415	ChlorPrep 3ml Tint
270715	ChlorPrep 10.5ml Tint
270815	ChlorPrep 26ml Tint
270449	SEPP 0.67ML
270299	FREPP 1.5ML
2604071	ChlorPrep 1.5ML CLEAR
270400	ChlorPrep 3ml Clear
270700	ChlorPrep 10.5ml Clear
270800	ChlorPrep 26ml Clear

ANTT[®]: aseptic non touch technique

*Compared with povidone iodine