ChloraPrep® patient preoperative skin preparation Nonsterile solution labeling

Frequently asked questions

Why is CareFusion updating the ChloraPrep® label to state "nonsterile solution"?

The U.S. Food and Drug Administration (FDA) held a public meeting on December 12, 2012, to gather comments on how to address microbial contamination of antiseptic drug products indicated for preoperative or pre-injection skin preparation. The FDA also wrote an article to raise awareness of the issue, which was published in the New England Journal of Medicine.[1]

In 2013, the FDA requested manufacturers of over-the-counter topical antiseptics make changes to their products in an ongoing effort to improve patient safety. The modifications included a request that manufacturers use single-use packaging and revise the product labels to indicate whether the antiseptic solution and applicator contained within the product is sterile or nonsterile for patient preoperative and preinjection skin preparation products. In response, CareFusion has developed a plan to update labels with "nonsterile solution" and educate customers on the difference between sterile solution and sterilization, and how it affects patient safety.

The FDA asked all manufacturers to voluntarily revise the product labels for topical antiseptics to indicate whether the drug is manufactured as a sterile or nonsterile product. CareFusion adhered to the request and submitted revised labeling to the FDA. CareFusion's actions are an effort to be transparent regarding this issue and lead an effort to educate clinicians and improve patient safety.

If ChloraPrep products are sterilized, why do they not contain sterile solution?

A product labeled as non sterile does not suggest that it is contaminated with bacteria; instead, its contents have not been sterilized individually. Though all ChloraPrep applicators are sterilized at the end of the manufacturing process, the solution inside of the applicators is not treated with a separate sterilization process and, therefore, is not sterile. Unless a product says "sterile solution" on the label, health care professionals should be aware that they are using a nonsterile solution product.

Has ChloraPrep ever been the cause of contamination causing patient infection?

No. ChloraPrep patient preoperative skin preparation products have never been documented as the cause of contamination causing patient infection. The safety and consistency of ChloraPrep is guaranteed through well-designed and controlled manufacturing and testing procedures including chemical analysis, microbial analysis, applicator integrity reviews and package testing. These steps ensure that each ChloraPrep applicator will consistently perform as intended.

Are any chlorhexidine gluconate (CHG)-based sterile products available on the market?

Currently, sterile chlorhexidine gluconate-based products are not available because an efficient method does not exist to sterilize these antiseptic solutions on a large scale and within a time frame that meets customer demand.

CareFusion

Has the ChloraPrep formulation changed?

ChloraPrep patient preoperative skin preparation has not changed and continues to be the trusted one-step, broad-spectrum antiseptic that reduces bacteria on the skin that can cause infection.

Are my patients at risk because the ChloraPrep solution is not sterile?

Patients are not at heightened risk because the ChloraPrep formulation and applicator have not changed. The ChloraPrep solution continues to be the only FDA-approved formulation of 2% CHG and 70% isopropyl alcohol (IPA) with a single-use applicator that has appeared in more than 20 peer-reviewed publications and shown to outperform iodine-based products.[2,3]

How do I get more detailed information on this label change?

Please contact your sales representative or call customer support 800.323.9088 or visit **carefusion.com/labelupdate.**

To learn more about the FDA request for companies to label products as sterile or nonsterile, visit **http://www.fda.gov/Drugs/DrugSafety/ucm374838.htm.**

References

1 Chang, C., Furlong, L. Microbial stowaways in topical antiseptic products. *N Engl J Med,* 2012, 367:2170–2173. **2** Saltzman, M.,Nuber, G., Gryzlo, S., Marecek, G. et al. Efficacy of surgical preparation solutions in shoulder surgery. *J Bone Joint Surg Am,* August 2009, 91(8): 1949–1953. **3** Ostrander, R., Botte, M., Brage, M. Efficacy of surgical preparation solutions in foot and ankle surgery. *J Bone Joint Surg Am,* May 2005, 87(5):980–985.

CareFusion
Vernon Hills, IL

carefusion.com

CareFusion