Safety

Over-the-Counter Topical Antiseptic Products: Drug Safety Communication - FDA Requests Label Changes and Single-Use Packaging to Decrease Risk of Infection

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AUDIENCE: Healthcare Professionals, Risk Managers, Pharmacy

ISSUE: The U.S. Food and Drug Administration (FDA) is requesting label and packaging changes to enhance the safe use of certain over-the-counter (OTC) topical antiseptic products. This request is the result of our ongoing evaluation of infrequent but continuing reports of infections resulting from antiseptic products labeled for preoperative or preinjection skin preparation. When used properly, topical antiseptics are safe and effective products to reduce the number of bacteria on patients' skin prior to surgery or injections. However, most often, contamination of topical antiseptics occurs when organisms are introduced into the product by users. Therefore, health care professionals and patients should follow all label directions to decrease the chances of infection.

Outbreaks associated with the use of contaminated topical antiseptics have been reported in the medical literature and to the Centers for Disease Control and Prevention (CDC). Clinical infections have also been reported to FDA, leading to some product recalls. The reported outcomes ranged from localized infections at injection sites to systemic infections that resulted in death. FDA has reviewed reports of four deaths, five cases of wound infection, seven cases of peritonitis, 10 cases of septic arthritis, 14 cases of indwelling catheters requiring replacement, 16 cases of injection site infection, and 32 cases of bacteremia. These infections have been confirmed to be caused by contaminated antiseptic products. Affected products included all commonly used antiseptic ingredients, including alcohol, iodophors, chlorhexidine gluconate, and quaternary ammonium products. Organisms implicated in the outbreaks included Bacillus cereus, Burkholderia cepacia, Pseudomonas aeruginosa, Achromobacter xylosoxidans, Ralstonia pickettii, Serratia marcescens, and Mycobacterium abscessus.

BACKGROUND: Over-the-counter (OTC) topical antiseptic drugs for use according to the label instructions to reduce the number of bacteria on the skin prior to surgery or injections. When used properly, over-the-counter (OTC) topical antiseptics are safe and effective products to reduce the number of bacteria on the skin prior to surgery or an injection. Commonly used products contain isopropyl or ethyl alcohol, povidone iodine, poloxamer iodine, benzalkonium chloride, benzethonium chloride, or chlorhexidine gluconate as a single agent or in combination with alcohol. These products are marketed as solutions, swabs, pads saturated with a solution, and applicators containing a solution. Currently available as both single-use and multiple-use products.

Topical antiseptics are not required to be manufactured as sterile and so may become contaminated with bacteria during manufacturing. Labeling stating a product is sterile means it was treated with a process during manufacturing to eliminate all potential microorganisms. However, even topical antiseptics manufactured with a sterile process, can become contaminated if proper care is not taken when using them. The term nonsterile on the product label means it was not sterilized during manufacturing; it does not mean the product contains harmful bacteria.

RECOMMENDATION: To further reduce the risk of infection with improper topical antiseptic use and the possibility of these products becoming contaminated with bacteria during use, we are requesting that manufacturers package antiseptics indicated for preoperative or preinjection skin preparation in single-use containers.

- To reduce the risk of infection, ensure the products are used according to the directions on the label.
- The antiseptics in these single-use containers should be applied only one time to one patient.
- We also recommend that health care professionals and patients do not dilute antiseptic products after opening them.
- Applicators and any unused solution should be discarded after the single application.

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