

RARE ALLERGIC REACTION TO TOPICAL CHLORHEXIDINE GLUCONATE

- The Food and Drug Administration has requested that manufacturers of over-the-counter topical products containing chlorhexidine gluconate add a warning to the drugs' labeling about the risk of a rare but potentially lethal allergic reaction to the antiseptic.
- If patients develop an allergic response to a product containing chlorhexidine gluconate, they should discontinue its use and wash any remaining product off their skin. Nurses should monitor patients and be prepared to treat anaphylaxis.

The Food and Drug Administration (FDA) has issued a *Drug Safety Communication* warning of possible serious allergic reactions, including anaphylaxis, to use of the antiseptic chlorhexidine gluconate (see Table 1 for a list of products containing the drug).

Chlorhexidine gluconate is a topical antiseptic frequently used as a wash in patient showers or baths before surgery; as a surgical skin prep in the operating room; and prior to central line insertion, injections, or other procedures to reduce the risk of skin bacteria being introduced into the bloodstream. Products containing the drug are often sold over the counter, although there is a prescription oral

rinse to treat gingivitis and a prescription oral chip to treat periodontal disease. Chlorhexidine gluconate can also be incorporated into dressings or intravenous lines in the manufacturing process. The labeling for the prescription products already contain a warning of potential serious allergic reactions to chlorhexidine gluconate. The FDA is now requesting that a similar warning be placed on the labeling for over-the-counter products.

To determine the number of anaphylactic reactions from use of topical chlorhexidine gluconate products, the FDA reviewed data from its Adverse Event Reporting System database, the medical literature, and the National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance and found a total of 52 case reports between January 1, 1969, and June 4, 2015. All cases involved serious allergic responses; half of the reactions were considered life threatening and two resulted in death. The reported events occurred on the same day the chlorhexidine gluconate product was used.

While the risks of allergic response and anaphylaxis with use of chlorhexidine gluconate are rare, nurses should always ask patients if they've had an allergic response to any antiseptic prior to recommending or prescribing a

chlorhexidine gluconate product. Povidone-iodine, alcohols, benzalkonium chloride, benzethonium chloride, or parachloro-metaxenol can be used in place of chlorhexidine gluconate if an allergy is known or suspected. If a patient has an unexplained allergic reaction during an injection, during surgery, or any time chlorhexidine gluconate is used, nurses should consider that chlorhexidine gluconate may have caused the response. In these cases, patients should stop use of the antiseptic immediately and wash any remaining product off their skin. Nurses should monitor the patient closely and promptly provide appropriate care for allergic responses. Nurses should also have emergency equipment on hand and be prepared to treat anaphylaxis.

Health care providers who encounter a suspected adverse response to chlorhexidine gluconate should contact the FDA MedWatch program at <http://bit.ly/1KGertT>. To read the *Drug Safety Communication* on chlorhexidine gluconate, go to <http://bit.ly/2kZ1Vqi>.

FDA WARNINGS NURSES CAN INCLUDE IN PATIENT EDUCATION

- The Food and Drug Administration is urging consumers to avoid the following over-the-counter products or unapproved products that are sold online: PNC-27, promoted as a cancer drug; homeopathic baby teething products; weight-loss products containing sibutramine; and sexual enhancement products containing sildenafil.

Table 1. Products Containing Chlorhexidine Gluconate

Types of Products	Trade Names
Over-the-counter topical solutions, washes, sponges, and swabs	Avagard, Bioscrub, Brian Care, CHG Scrub, Chloraprep, CIDA-Stat, Dyna-Hex, Exidine, Hibiclen, Hibistat, Pharmaseal Scrub Care, Prevacics
	Generic products are also available, including store brands.
Prescription oral rinse	Peridex
	Generic brands include Oris, Paroex, Periogard, PerioRx.
Prescription oral chip	Periochip

The Food and Drug Administration (FDA) frequently offers warnings regarding the safety of over-the-counter (OTC) or unapproved consumer products. Here are some recent warnings