OPTUMRx®

Chlorhexidine Gluconate – Safety Update

- On February 2, 2017, the FDA announced that manufacturers of over-the-counter (OTC) antiseptic products containing chlorhexidine gluconate are required to add a warning about the risk of rare, but serious allergic reactions reported with these products to the Drug Facts labels.
    - These reactions can occur within minutes of exposure, and can occur with topical or oral exposure to the drug.
- Chlorhexidine gluconate is mainly available in OTC products to clean and prepare the skin before surgery and before injections in order to help reduce bacteria that potentially can cause skin infections. These products are available as solutions, washes, sponges, and swabs.
    - Examples of OTC brand names include Avagard™, Bioscrub™, Brian Care™, CHG Scrub™, ChloraPrep®, CIDA-Stat™, Dyna-Hex®, Exidine™, Hibiclens®, Hibistat®, Pharmaseal Scrub Care™, and Prevantics®. They are also sold as generic products, including through store brands.
- Chlorhexidine gluconate is also available as a prescription mouthwash to treat gingivitis and as a prescription oral chip to treat periodontal disease (eg, Peridex™, Periogard®, PerioRx™, Paroex®, Oris®, and Periochip®). Some medical devices such as dressings and intravenous lines also contain chlorhexidine gluconate.
    - Prescription chlorhexidine gluconate mouthwashes and oral chips already contain a warning about the possibility of serious allergic reactions in their labels.
- FDA recommendations for healthcare providers:
    - Patients should be asked if they have ever had an allergic reaction to any antiseptic before recommending or prescribing a chlorhexidine gluconate product.
    - Patients should be advised to seek immediate medical attention if they experience any symptoms of an allergic reaction when using chlorhexidine gluconate products.
    - If a patient exhibits an unexplained allergic reaction prior to or during an injection or surgical procedure, it should be verified whether chlorhexidine gluconate was used.
    - If it is suspected that a patient may have (or has had) an allergic reaction to chlorhexidine gluconate, the reaction should be monitored carefully, immediate respiratory and/or cardiovascular support should be provided as needed, and the drug or medical device containing chlorhexidine gluconate should be discontinued as expeditiously as possible.
    - Alternative antiseptics such as povidone-iodine, alcohols, benzalkonium chloride, benzethonium chloride, or parachlorometaxylenol may be considered when any previous allergy to chlorhexidine gluconate is documented or suspected.
- FDA recommendations for patients:
    - Patients should inform their healthcare provider if they have ever had an allergic reaction to any antiseptics applied to the skin, prescription mouthwashes, or when using a medical device containing chlorhexidine gluconate.
    - Patients should stop using the product containing chlorhexidine gluconate and seek immediate medical attention if they experience symptoms of a serious allergic reaction such as wheezing or difficulty breathing, swelling of the face, hives that can quickly progress to other more serious symptoms, severe rash, and shock.

Continued . . .

- The safety update is based on cases identified from national databases and the medical literature.
    - The FDA identified 52 cases of anaphylaxis with the use of chlorhexidine gluconate products applied to the skin.
    - The serious allergic reaction cases reported outcomes that required emergency department visits or hospitalizations to receive drugs and other medical treatments. These allergic reactions resulted in two deaths.