NATIONAL PBM BULLETIN

FEBRUARY 7, 2017

DEPARTMENT OF VETERANS AFFAIRS
PHARMACY BENEFITS MANAGEMENT SERVICES (PBM), MEDICAL ADVISORY PANEL (MAP),
VISN PHARMACIST EXECUTIVES (VPEs), AND THE CENTER FOR MEDICATION SAFETY (VA MedSAFE)

Alerts are based on the clinical evidence available at the time of publication. Recommendations are intended to assist practitioners in providing consistent, safe, high quality, and cost effective drug therapy. They are not intended to interfere with clinical judgment. When using dated material, the clinician should consider new clinical information, as available and applicable.

CHLORHEXIDINE GLUCONATE SAFETY

I. ISSUE

FDA is requesting the manufacturers of over-the-counter (OTC) antiseptic products containing chlorhexidine gluconate to add a warning about the risk of serious allergic reactions to the Drug Facts labels. Although rare, serious allergic reactions, including fatal anaphylaxis, can develop within minutes of exposure, and can occur with topical or oral use of the drug.

II. BACKGROUND

Prescription chlorhexidine gluconate mouthwashes for gingivitis and oral chips used for periodontal disease already contain a warning about the possibility of serious allergic reactions in their labels. However, since the number of reports of serious allergic reactions to these products has increased over the last several years, FDA is extending the warning to the OTC products containing chlorhexidine gluconate as well, which includes topical solutions, washes, sponges, and swabs. They are marketed under brand names such as Avagard, Bioscrub, Brian Care, CHG Scrub, ChloraPrep, CIDA-Stat, Dyna-Hex, Exidine, Hibiclens, Hibistat, Pharmaseal Scrub Care, and Prevantics. They are also available as generic products and store brands. Some medical devices such as dressings and intravenous lines also contain chlorhexidine gluconate.

III. DISCUSSION

FDA identified 43 worldwide cases reported in the FDA Adverse Event Reporting System (FAERS) database from January 1, 1969, through June 4, 2015, of anaphylactic reaction with the use of chlorhexidine gluconate topical products.

- 24 were reported after 2010.
- All were serious:
  - 26 classified as life-threatening,
  - 12 required hospitalization, and
  - 2 deaths attributed to the anaphylactic reaction.
  - 39 involved hypotension in association with either skin, respiratory, or gastrointestinal symptoms.
  - 12 involved elevated histamine or tryptase levels.
- All reported that the reaction occurred the same day the product was used, and seven reported a positive allergy rechallenge.

IV. PROVIDER CONSIDERATIONS/RECOMMENDATIONS

FDA recommends that healthcare professionals:

- Inquire from patients if they have experienced any reaction to the ingredient chlorhexidine gluconate or to antiseptic products containing chlorhexidine gluconate prior to use, such as:
  - Wheezing or difficulty breathing
  - Swelling of the face
  - Hives that can quickly progress to other more serious symptoms
  - Severe rash
  - Shock

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CHLORHEXIDINE GLUCONATE SAFETY *(continued from page 1)*

- If a patient exhibits an unexplained allergic reaction prior to or during an injection or surgical procedure:
  - check whether chlorhexidine gluconate was used,
  - monitor the reaction carefully,
  - provide immediate respiratory and/or cardiovascular support as needed, and
  - discontinue the use of the drug or medical device containing chlorhexidine gluconate immediately.
- Consider using alternative antiseptics such as povidone-iodine, alcohols, benzalkonium chloride, benzethonium chloride, or parachlorometaxylenol (PCMX) when any previous allergy to chlorhexidine gluconate is documented or suspected.

Providers should continue to report any adverse reactions with the use of chlorhexidine gluconate by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800-FDA-0178, online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm, or by mail).

V. REFERENCES

FDA Drug Safety and Availability. FDA Drug Safety Communication: FDA warns about rare but serious allergic reactions with the skin antiseptic chlorhexidine gluconate. http://www.fda.gov/Drugs/DrugSafety/ucm530975.htm (Accessed February 2, 2017).

ACTIONS

- ***Facility Director*** *(or physician designee): Forward this document to the Facility Chief of Staff (COS).*
- ***Facility COS and Chief Nurse Executives:*** *Forward this document to all appropriate providers and health care staff (e.g.,* ***primary care providers, surgical service, anesthesia, emergency department staff, including contract providers, etc****.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.*
- ***ACOS for R&D:*** *Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).*