FDA Drug Safety Communication: FDA warns about rare but serious allergic reactions with the skin antiseptic chlorhexidine gluconate

[2-2-2017]

Safety Announcement

The U.S. Food and Drug Administration (FDA) is warning that rare but serious allergic reactions have been reported with the widely used skin antiseptic products containing chlorhexidine gluconate. Although rare, the number of reports of serious allergic reactions to these products has increased over the last several years. As a result, we are requesting the manufacturers of over-the-counter (OTC) antiseptic products containing chlorhexidine gluconate to add a warning about this risk to the **Drug Facts labels (/Drugs/ResourcesForYou/Consumers/ucm143551.htm)**. Prescription chlorhexidine gluconate mouthwashes and oral chips used for gum disease already contain a warning about the possibility of serious allergic reactions in their labels.

Patients and consumers should stop using the product that contains chlorhexidine gluconate and seek medical attention immediately or call 911 if they experience symptoms of a serious allergic reaction. These reactions can occur within minutes of exposure. Symptoms include wheezing or difficulty breathing; swelling of the face; hives that can quickly progress to more serious symptoms; severe rash; or shock, which is a life-threatening condition that occurs when the body is not getting enough blood flow.

Health care professionals should always ask patients if they have ever had an allergic reaction to any antiseptic before recommending or prescribing a chlorhexidine gluconate product. Advise patients to seek immediate medical attention if they experience any symptoms of an allergic reaction when using the products. 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.

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 and under many different brand names and as generics (see Facts about Chlorhexidine Gluconate). Chlorhexidine gluconate is also available as a prescription mouthwash to treat gingivitis and as a prescription oral chip to treat periodontal disease. In 1998, we issued a Public Health Notice to warn health care professionals about the risk of serious allergic reactions with medical devices such as dressings and intravenous lines that contain chlorhexidine gluconate.

We identified 52 cases of anaphylaxis, a severe form of allergic reaction, with the use of chlorhexidine gluconate products applied to the skin. In the 46 years between January 1969 and early June 2015, FDA received reports of 43 cases worldwide.* More than half of the 43 cases were reported after 2010, and after our 1998 Public Health Notice. This number includes only reports submitted to FDA, so there are likely additional cases about which we are unaware. The serious allergic reaction cases reported outcomes that required emergency department visits or hospitalizations to receive drug and other medical treatments. These allergic reactions resulted in two deaths. Eight additional cases of anaphylaxis were published in the medical literature between 1971 and 2015,[1-3] and one case was identified in the **National Electronic Injury Surveillance System-Cooperative Adverse Drug Event Surveillance (NEISS-CADES) database (http://www.healthindicators.gov/Resources/DataSources/NEISS-CADES_86/Profile)** between 2004 and 2013.

We urge patients, consumers, and health care professionals to report side effects involving chlorhexidine gluconate or other medicines to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page.

*The cases were reported to the **FDA Adverse Event Reporting System (FAERS) (/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm2007060.htm)**.

Facts about Chlorhexidine Gluconate

Additional Information for Patients and Consumers

Additional Information for Health Care Professionals

Data Summary

References

en Español (/Drugs/DrugSafety/ucm540855.htm)

Drug Safety Communication (/downloads/Drugs/DrugSafety/UCM539059.pdf) (PDF - 67KB)

Related Information

- **OTC Drug Facts Label (/Drugs/ResourcesForYou/Consumers/ucm143551.htm)**
- **What's on the Label (high resolution) (PDF - 546KB) (/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/UCM285993.pdf)**
- **The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective (/Drugs/ResourcesForYou/Consumers/ucm143534.htm)**
- **Think It Through: Managing the Benefits and Risks of Medicines (/Drugs/ResourcesForYou/Consumers/ucm143558.htm)**

Contact FDA

For More Info
855-543-DRUG (3784)
and press 4
druginfo@fda.hhs.gov (mailto:druginfo@fda.hhs.gov)

Report a Serious Problem to MedWatch
Complete and submit the report **Online (https://www.accessdata.fda.gov/scripts/medwatch/)**.
Download form (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

More in Drug Safety and Availability (/Drugs/DrugSafety/default.htm)

Drug Alerts and Statements (/Drugs/DrugSafety/ucm215175.htm)

Medication Guides (/Drugs/DrugSafety/ucm085729.htm)

Drug Safety Communications (/Drugs/DrugSafety/ucm199082.htm)

Drug Shortages (/Drugs/DrugSafety/DrugShortages/default.htm)

Postmarket Drug Safety Information for Patients and Providers (/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/default.htm)

Information by Drug Class (/Drugs/DrugSafety/InformationbyDrugClass/default.htm)

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Drug Recalls (/Drugs/DrugSafety/DrugRecalls/default.htm)

Drug Supply Chain Integrity (/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/default.htm)