



Chlorhexidine Gluconate: Drug Safety Communication – Rare But Serious Allergic Reactions

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FDA 發布了一則安全警訊，含有 chlorhexidine gluconate 成分的殺菌產品有罕見但嚴重的過敏反應，雖然罕見，但根據 FDA 藥物不良反應通報的資料庫，這些產品的嚴重過敏反應在過去幾年有增加的趨勢。

含 Chlorhexidine gluconate 成分的非處方成藥主要是用於術前和注射前皮膚的清潔，用以預防皮膚感染，另外也有用於治療牙齦炎的嗽口水。

FDA 要求含 Chlorhexidine gluconate 的成藥製造商於藥物成分標籤新增有嚴重過敏反應的警語。

建議：

醫療人員在給予 Chlorhexidine gluconate 殺菌劑前應該詢問患者是否對任何殺菌劑有過敏反應，如果懷疑或對 Chlorhexidine gluconate 有過敏紀錄的患者，應該改用其他的抗菌劑，如 povidone-iodine, alcohols, benzalkonium chloride, benzethonium chloride, 或 parachlorometaxyleneol (PCMX)

建議患者如果在使用 Chlorhexidine gluconate 殺菌劑後有任何過敏反應的症狀時應該立即停用並盡速就醫。過敏反應可能在使用殺菌劑後幾分鐘內發生，症狀包括哮喘或呼吸困難、臉部腫脹、蕁麻疹、嚴重皮疹甚至是休克。

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AUDIENCE: Nursing, Surgery, Dentistry, Patient

ISSUE: 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. See the FDA Drug Safety Communication for a data summary.

As a result, FDA is 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.

BACKGROUND: 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. Chlorhexidine gluconate is also available as a prescription mouthwash to treat

gingivitis and as a prescription oral chip to treat periodontal disease.

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.

In 1998, FDA 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.

RECOMMENDATION: 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 parachlorometaxlenol (PCMX) when any previous allergy to chlorhexidine gluconate is documented or suspected.

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.