



Food and Drugs Authority

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RARE BUT SERIOUS ALLERGIC REACTIONS WITH THE SKIN ANTISEPTIC CHLORHEXIDINE GLUCONATE

The National Pharmacovigilance Centre, Food and Drugs Authority (FDA) wishes to inform healthcare professionals and consumers that it has become aware of rare but serious allergic reactions associated with use of skin antiseptic products containing chlorhexidine gluconate that was published by the US Food and Drugs Administration on February 2, 2017. These reactions which could occur within minutes of exposure to the products include difficulty breathing, swelling of the face, hives, severe rash or shock.

Chlorhexidine gluconate may be found in both over-the-counter and prescription products. Prescription medicines containing chlorhexidine gluconate include mouthwashes and oral chips used for gum disease while over-the-counter products include topical solutions, washes, sponges and swabs.

The Food and Drugs Authority has registered both prescription and over-the-counter products containing chlorhexidine gluconate (Table 1 below), however the Authority has not received any reports of adverse drug reactions from consumers and healthcare professionals.

Advice for Consumers:

Patients and consumers are advised to stop using products containing chlorhexidine gluconate and immediately consult their healthcare provider if they experience symptoms of serious allergic reaction.

Advice for healthcare professionals:

Healthcare professionals should enquire about past allergic reactions to any antiseptic before recommending or prescribing a chlorhexidine gluconate product. Alternative antiseptics such as povidone-iodine, alcohols, benzalkonium chloride, benzethonium chloride or parachlorometaxyleneol could be recommended if there is documented or suspected history of allergy to chlorhexidine gluconate.

Additionally, healthcare professionals and consumers are encouraged to be more vigilant when using such products and report any untoward effect to the National Pharmacovigilance Centre through the underlisted means:

E-mail : drug.safety@fdaghana.gov.gh

Healthcare professionals : <http://adr.fdaghana.gov.gh/>

Consumers : <http://adr.fdaghana.gov.gh/patient.php>

SMS Short code **4015**

Table 1: List of Products Containing Chlorhexidine Gluconate

No	Product Name	Ingredients	Dosage Form
1	Parodontax Extra	Chlorhexidine Gluconate	Mouthwash (Oral Rinse)
2	Hibiscrub	Chlorhexidine Gluconate	Topical Solution
3	Corsodyl Mouthwash	Chlorhexidine Gluconate	Mouthwash (Oral Rinse)
4	Savlon	Chlorhexidine Gluconate + Cetrimide	Topical Solution
5	Savlon	Chlorhexidine Gluconate + Cetrimide	Topical Cream
6	Mycil	Chlorhexidine Gluconate + Tolnaftate	Powder for Topical Use
7	Micobact	Chlorhexidine Gluconate + Miconazole Nitrate	Powder for Topical Use
8	Quadrajel	Chlorhexidine Gluconate + Lidocaine + Tronidazole	Oral Gel
9	Hibitane	Chlorhexidine Gluconate	Topical Solution
10	Benol	Chlorhexidine Gluconate + Cetrimide	Topical Solution
11	Aya Mouthwash	Chlorhexidine Gluconate	Mouthwashes (Oral Rinse)
12	Parodontosan	Chlorhexidine Digluconate	Mouthwashes (Oral Rinse)
13	Chlorhexidine Gluconate Microbicidal Hand Scrub	Chlorhexidine Gluconate	Topical Solution