

# Advice for Patients: Denture Cleansers

Issued: February 14, 2008

FDA is asking the manufacturers of denture cleansers to revise labeling and to consider appropriate alternatives to an ingredient in their products. This action is in response to reports of 73 severe reactions linked to these cleansers, including at least one death.

The ingredient, persulfate, which is known to cause allergic reactions, is the most likely cause of the problem according to literature and research. Persulfates are used in these products as part of the cleaning and bleaching process.

Other reactions may be due to product misuse. The labeling revisions are needed to ensure that denture wearers clearly understand that these products are to clean dentures in a container-- not while still in the mouth. For example, some cleansers that contain mouthwash are described as minty fresh, or they may have graphics such as fizzing bubbles. This may mislead consumers by implying that the product may be chewed, gargled or swallowed.

## Who is at Risk?

- People who are allergic to persulfates. (All users should be aware that this kind of allergic reaction may not occur after the first use or even until many years of use. Also some symptoms may not appear for several minutes or even hours after actual use.)
- People who are unable to read or understand the product label. Examples include those with poor eyesight or with a condition such as Alzheimer's disease which compromises cognitive ability.

## What Are the Symptoms of Reaction?

Allergic reactions can occur with both proper and improper use of these cleansers. Reactions may become more frequent and severe with repeated use of the product.

Symptoms of an allergic reaction may include:

- Irritation
- Tissue damage
- Rash
- Hives
- Gum tenderness
- Breathing problems
- Low blood pressure

Symptoms from product misuse may include:

- Damage to the esophagus
- Abdominal pain
- Burns
- Breathing problems
- Low blood pressure
- Seizures
- Bleaching of tissue
- Blood in the urine
- Internal bleeding
- Vomiting

### **What Should Denture Wearers Do?**

- Read all instructions carefully
- Never chew, swallow, or gargle with denture cleansers
- Always thoroughly rinse dentures and other dental appliances before placing in the mouth
- Remember that reactions might not occur right away
- If symptoms do occur, remove dentures and contact the prescribing dentist
- Ask the prescribing dentist about using an alternative method for cleaning dentures

For more information see [Public Health Notification: Denture Cleanser Allergic Reactions and Misuse](#)<sup>1</sup>.

Health care professionals and consumers may report adverse reactions or quality problems experienced with the use of this product to FDA's MedWatch Adverse Event Reporting program online, by mail or by FAX.

- Online: [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#)<sup>2</sup>
- Mail: use postage-paid FDA form 3500, information available at: [Instructions for Completing Form FDA 3500](#)<sup>3</sup> Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
- FAX: 1-800-FDA-0178