Generic Name:
Benzocaine
Trade Name:
Multiple trade names
Company:
Multiple companies
Notes:

FDA is warning that OTC teething products containing the pain reliever benzocaine pose a serious risk of methemoglobinemia in infants and children younger than 2 years old and should no longer be used, marketed, or sold.

This dangerous condition is the result of elevated levels of methemoglobin in the blood and can lead to death. It causes the amount of oxygen carried through the blood to be greatly reduced.

Benzocaine is marketed to help relieve pain from a variety of conditions such as teething, sore throat, canker sores, and irritation of the mouth and gums. The products are sold as gels, sprays, ointments, solutions, and lozenges under the OTC brand names Anbesol, Baby Orajel, Cepacol, Chloraseptic, Hurricaine, Orabase, Orajel and Topex, as well as store brands and generics.

Signs and symptoms of methemoglobinemia include pale or gray- or blue-colored skin, lips, and nail beds; shortness of breath; fatigue; headache; lightheadedness; and rapid heart rate. These adverse effects may occur after using benzocaine for the first time or after prior uses and may appear within minutes to 1 to 2 hours after using benzocaine. If any of these symptoms occur, the person should receive medical attention immediately.

FDA is requiring manufacturers of all FDA-approved prescription local anesthetics to standardize warning information about the risk of methemoglobinemia in product labeling across this class of products. Manufacturers of approved, prescription local anesthetics will have 30 days to reply to FDA?s letter about these new safety labeling dhanges. If companies do not comply, FDA stated it will initiate a regulatory action to remove these products from the market. Also, the agency is requesting that companies add new warnings to all other benzocaine oral health products to describe certain serious risks.

FDA also previously cautioned parents and caregivers to not give certain homeopathic teething tablets to children and to seek advice from their health professional for safe alternatives.

When buying OTC oral health drug products, consumers should refer to the OTC Drug Facts Label to see if benzocaine is an active ingredient.

For advice on treating teething pain, FDA suggests the American Academy of Pediatrics? (AAP) recommendations.

Medication Monitor Categories:
Alerts and Recalls