Benzocaine Topical Products

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What are oral numbing agents?

Oral numbing agents, such as Orajel® and Anbesol®, are medications that can be applied directly (topically) to the surface of the mouth and gums (oral mucosa) to relieve pain from toothaches, canker sores, and braces. The active ingredient in these products is benzocaine, a local anesthetic that causes numbness in the area where it is applied by blocking nerve pain signals. Orajel® Adult contains twice as much benzocaine as Anbesol® Adult (20% versus 10%). These topical benzocaine products are widely used by older children and adults with mouth pain. They are primarily found in gel form but are also available as a liquid, spray, or lozenge.

How do I use an oral numbing agent?

Oral numbing medications are applied directly to the affected area. Follow the directions on the product label or the directions provided by your pharmacist or physician. Use the smallest amount necessary to relieve pain, and use it no more than the number of times recommended daily. Avoid getting it into your eyes.

How much oral numbing medication can I use?

Since the amount used that may result in a dangerous (toxic) reaction is not clearly known, it is important not to overuse the medication (please see 'Are oral numbing gels dangerous?'). For adults, product labels generally recommend using only small amounts, at most 4 times daily, for a maximum of 7 days. For infants under one year of age, as little as ½ teaspoon of 7.5% gel (100mg) and, in older children, approximately ½ teaspoon of 7.5% gel (greater than 240mg) have been associated with severe poisoning.

Are oral numbing medications dangerous?

Oral numbing medications are capable of causing severe side effects if used incorrectly. Adverse effects include, but are not limited to, headaches, feeling tired or dizzy,

confusion, fast heart rate (tachycardia), abnormal heartbeats (dysrhythmias), seizures, shortness of breath, lightheadedness, hives, facial swelling, burning or stinging sensation where the medicine was applied, or gray/blue colored skin. Any of these symptoms can be indicative of a more severe reaction. The skin discoloration is a sign of a condition called methemoglobinemia, which starves the body's tissues of oxygen and may be fatal when severe. According to a report by the U.S. Food and Drug Administration (FDA), children younger than 2-years-old may be at increased risk of developing methemoglobinemia. The FDA therefore does not recommend using benzocaine-containing oral numbing medications in children aged 2 years and younger except under the supervision of a healthcare professional. For more information on FDA recommendations about over-the-counter oral numbing medications, see the following link: http://www.fda.gov/Drugs/DrugSafety/ucm250029.htm

What happens if someone I know uses too much topical benzocaine?

If you are afraid that you or someone you know might have used too much of an oral numbing product, call your local Poison Control Center at 1-800-222-1222. There are overdose specialists at poison centers who can provide you with guidance and directions. It might be necessary to go to the emergency department for further evaluation and treatment.

Can I use adult oral numbing medications on an infant or child?

Adult oral numbing gels <u>cannot</u> be used for an infant or child. Adult forms of this medication contain a larger amount of benzocaine than the infant forms (10-20% versus 7.5%) and can lead to serious side effects. Additionally, the FDA does not recommend the use of benzocaine-containing oral numbing gels in children younger than 2 years (see "Are oral numbing medications dangerous?" above). In children older than 2 years, only the minimum amount necessary to relieve pain should be used. Contact your child's doctor before starting them on an oral numbing gel.

Will my other medications interact with oral numbing medications?

It is unlikely that other medications taken orally or by injection will have an effect on oral numbing medications or will be affected by them. However, you should always inform your doctor about any medications you currently use or are planning to start. This includes vitamins, herbal supplements, over-the-counter, and prescription medications.

Are oral numbing medications safe to use during pregnancy?

Oral numbing gels are considered a Pregnancy Category C drug, which means animal studies have shown the drugs to have bad effects on the fetus. There are no adequate studies in humans. If you are pregnant or planning to become pregnant, speak to your doctor about the risks and benefits <u>before</u> starting any oral numbing gel.

Are there any other safety facts I should know about oral numbing medications? Oral numbing medications should not be used if the imprinted bottle safety seal is damaged or missing. Avoid using these products for more than a few days unless instructed to by a doctor or dentist. Do not use these products if you have ever previously

instructed to by a doctor or dentist. Do not use these products if you have ever previousl had methemoglobinemia. Ask your doctor before starting any oral numbing agent in

children. Keep these products (and all other medications) out of the reach of children, and do not leave children unsupervised with these products.

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