

June 29, 2018

COM-2018-013

Dear provider of pharmaceutical services,

Receive kind greetings from PharmPix.

This communication is being sent to you to inform that an important correction has been made on a statement on our communication from May 2018, regarding the warning published by the Food and Drug Administration (FDA) for OTC Benzocaine Teething Products.

CORRECTION STATEMENT

- **Previous statement:** “Homeopathic teething products should also be avoided, due to the risk of adverse effects.”
- **Corrected statement:** “Certain homeopathic teething products should also be avoided, due to the risk of adverse effects.”

The correction has been made because only certain homeopathic teething products should be avoided, due to the risk of adverse effects.

Attached you will find the communication with the corrected statement. In addition, the communication has been corrected on our website. We strongly recommend you eliminate any copy of the previous version to avoid confusions.

For details regarding this and other safety issues, you can visit FDA’s website: www.fda.gov. In addition, if you have any doubt or wish to have more information regarding this document, you can call us to 787-522-5252, extension 138.

Regards,

Pharmacy Department

May 28, 2018

COM-2018- 010

Dear provider of pharmaceutical services,

The U.S. Food and Drug Administration (FDA) is warning that **over-the-counter (OTC) teething products containing benzocaine pose a serious risk to infants and children younger than 2 years.** Benzocaine can cause methemoglobinemia, a dangerous condition where the amount of oxygen carried through the blood is reduced and which can be life-threatening and result in death.

OTC teething products containing benzocaine 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.

The FDA announced that these products should no longer be marketed for use as teething pain reliever in infants and children younger than 2 years and is asking companies to stop selling these products for this use. In addition, the FDA is requiring that companies add new warnings to all other benzocaine oral products to describe certain risks.

<div style="border: 1px solid #ccc; border-radius: 15px; background-color: #e6f2ff; padding: 10px; width: 80%; margin: auto;"> <h3 style="margin: 0;">Warning</h3> <div style="border: 1px solid #0056b3; background-color: #0056b3; color: white; padding: 10px; margin: 10px auto; width: 80%;"> <p style="margin: 0; font-size: 1.2em;">Methemoglobinemia</p> </div> </div>	<div style="border: 1px solid #ccc; border-radius: 15px; background-color: #e6f2ff; padding: 10px; width: 80%; margin: auto;"> <h3 style="margin: 0;">Contraindications</h3> <div style="border: 1px solid #00a651; background-color: #00a651; color: white; padding: 10px; margin: 10px auto; width: 80%;"> <p style="margin: 0; font-size: 1.2em;">Not to use for teething</p> </div> <div style="border: 1px solid #00a651; background-color: #00a651; color: white; padding: 10px; margin: 10px auto; width: 80%;"> <p style="margin: 0; font-size: 1.2em;">Not to use in infants and children younger than 2 years</p> </div> </div>
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Pharmacists can play an important role in educating parents and caregivers on the dangers of benzocaine teething products, and to recommend safe ways to relieve teething pain in infants and children. Below are listed some key points regarding patient counseling and teething recommendations:

- Avoid using benzocaine, and other local anesthetics to treat teething pain in infants and children younger than 2 years.
 - Benzocaine products are not effective for teething since they wash out of the mouth within minutes.
- Importance of reading the drug facts label to verify if the product contains benzocaine.
 - The OTC benzocaine products should only be used sparingly in adults, and children 2 years and older and not more than four times a day.
- American Academy of Pediatrics recommendations for teething pain:
 - Gently rub or massage the child’s gums with one finger
 - Use a firm rubber teething ring
- Certain homeopathic teething products should also be avoided, due to the risk of adverse effects.

- Signs and symptoms of methemoglobinemia.
 - Pale, gray, or blue-colored skin, lips, and nailbeds
 - Shortness of breath
 - Fatigue
 - Confusion
 - Headache
 - Lightheadedness
 - Tachycardia

For more information regarding the FDA warning against the use of OTC benzocaine teething products visit the FDA website (www.fda.gov).

On PharmPix we are compromised with the health and wellness of our insured. It is our priority to offer high quality services and to promote practices for health promotion and diseases prevention. If you have any doubt or wish to have more information regarding this document, you can call us to 787-522-5252, extension 138.

Regards,

Pharmacy Department

References:

1. Risk of serious and potentially fatal blood disorder prompts FDA action on oral over-the-counter benzocaine products used for teething and mouth pain and prescription local anesthetics. (May 23, 2018). Available at: <https://www.fda.gov/Drugs/DrugSafety/ucm608265.htm>
2. FDA takes action against the use of OTC benzocaine teething products due to serious safety risk, lack of benefit. (May 23, 2018). Available at: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm608325.htm>
3. FDA Warns Against Using OTC Benzocaine Teething Products. Pharmacy Times. (May 23, 2018). Available at: <https://www.pharmacytimes.com/contributor/jennifer-gershman-pharmd-cph/2018/05/fda-warns-against-using-otc-benzocaine-teething-products>

