

**EXAMPLE OTC DRUG FACTS LABELING FOR ORAL HEALTH CARE DRUG PRODUCTS CONTAINING BENZOCAINE INTENDED FOR ADULTS AND CHILDREN 2 YEARS AND OLDER**

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose[s]</b>
Benzocaine XX <sup>1</sup> .....	XXXXX <sup>1</sup>
<b>Use[s]</b>	
XXXXX <sup>1</sup>	
<b>Warnings</b>	
<b>Methemoglobinemia warning:</b>	
Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:	
<ul style="list-style-type: none"> <li>• pale, gray, or blue colored skin (cyanosis)</li> <li>• headache</li> <li>• rapid heart rate</li> <li>• shortness of breath</li> <li>• dizziness or lightheadedness</li> <li>• fatigue or lack of energy</li> </ul>	
<b>Allergy alert:</b> do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics.	
<b>Flammability warning [if applicable see 21 CFR 201.66(c)(5)(ii)(C)]</b>	
<b>Sore throat warning:</b> [if applicable see OHDP TFM] if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persist or worsens, see your dentist or doctor promptly.	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>• XXXXX<sup>1</sup></li> <li>• for teething</li> <li>• in children under 2 years of age</li> </ul>	
<b>When using this product</b>	
[if applicable see 21 CFR (c)(5)(vi)]	
<b>Stop use and ask a doctor if</b>	
[if applicable see 21 CFR(c)(5)(vii)]	
<b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away	
<b>Directions</b>	
[Directions appear in tabular format when dosage instructions are provided for three or more age groups or populations.]	
adults and children 2 years of age or older	XXXXX <sup>1</sup>
children between 2 and 12 years of age	XXXXX <sup>1</sup>
children under 2 years of age	do not use
[Or, directions can be presented using bulleted statements when dosage directions are provided for one or two age groups or populations.]	
<ul style="list-style-type: none"> <li>• adults and children 2 years of age and older: XXXXX<sup>1</sup></li> <li>• children under 2 years of age: do not use</li> </ul>	
<b>Other information</b>	
[Insert any additional information that is not included under the other subheadings but which is required or is made optional under an OTC drug monograph(s), other OTC drug regulation(s), approved drug application, statute, or OTC drug guidance.]	
<b>Inactive ingredients</b>	
[Insert a list of each inactive ingredient, using its established name.]	
<b>Questions or Comments?</b>	
[Insert optional heading used to provide a telephone number of a source to answer questions about the drug product or to receive reports of adverse events associated with the use of the drug product.]	

[ ] Text within brackets is intended to serve as instructions for content, if and where applicable.

<sup>1</sup>(Depending on drug product, insert as described in Oral Health Care Drug Products TFM (56 FR 48302, September 24, 1991). Note that any teething-related indication will not be an appropriate use for the product)