

Summary of proposed changes to **Warnings** section of the Drug Facts panel with changes highlighted in red.

New/Revised Warnings	Previous Warnings
<p><b>Warnings</b>  <b>Allergy alert:</b> Ibuprofen may cause a severe allergic reaction which may include:</p> <ul style="list-style-type: none"> <li>• hives</li> <li>• facial swelling</li> <li>• asthma (wheezing)</li> <li>• shock</li> </ul> <p><b>Stomach bleeding warning:</b> Taking more than recommended may cause stomach bleeding.  <b>Sore throat warning:</b> Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by doctor.</p>	<p><b>Warnings</b>  <b>Allergy alert:</b> Ibuprofen may cause a severe allergic reaction which may include:</p> <ul style="list-style-type: none"> <li>• hives</li> <li>• facial swelling</li> <li>• asthma (wheezing)</li> <li>• shock</li> </ul> <p><b>Sore throat warning:</b> Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by doctor.</p>
<p><b>Do not use</b> if the child has ever had an allergic reaction to any other pain reliever/fever reducer</p>	<p><b>Do not use</b> if you have ever had an allergic reaction to any other pain reliever/fever reducer</p>
<p><b>Ask a doctor before use if the child has</b></p> <ul style="list-style-type: none"> <li>• not been drinking fluids</li> <li>• bleeding problems</li> <li>• lost a lot of fluid due to continued vomiting or diarrhea</li> <li>• problems or serious side effects from taking fever reducers or pain relievers</li> <li>• stomach problems that last or come back, such as heartburn, upset stomach or pain</li> <li>• high blood pressure, heart or kidney disease or is taking a diuretic</li> </ul>	<p><b>Ask a doctor before use if the child has</b></p> <ul style="list-style-type: none"> <li>• not been drinking fluids</li> <li>• lost a lot of fluid due to continued vomiting or diarrhea</li> <li>• stomach pain</li> <li>• problems or serious side effects from taking fever reducers or pain relievers</li> </ul>
<p><b>Ask a doctor or pharmacist before use if the child is</b></p> <ul style="list-style-type: none"> <li>• under a doctor's care for any serious medical condition</li> <li>• taking any other product that contains ibuprofen, or any other pain reliever/fever reducer</li> <li>• taking a prescription drug for anticoagulation (blood thinning)</li> <li>• taking any other drug</li> </ul>	<p><b>Ask a doctor or pharmacist before use if the child is</b></p> <ul style="list-style-type: none"> <li>• under a doctor's care for any serious medical condition</li> <li>• taking any other product that contains ibuprofen, or any other pain reliever/fever reducer</li> <li>• taking any other drug</li> </ul>
<p><b>When using this product</b> give with food or milk if stomach upset occurs</p>	<p><b>When using this product</b> give with food or milk if stomach upset occurs</p>
<p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>• an allergic reaction occurs. Seek medical help right away.</li> <li>• fever or pain gets worse or lasts more than 3 days</li> <li>• stomach pain or upset gets worse or lasts</li> <li>• redness or swelling is present in the painful area</li> <li>• any new symptoms appear</li> </ul>	<p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>• an allergic reaction occurs. Seek medical help right away.</li> <li>• fever or pain gets worse or lasts more than 3 days</li> <li>• stomach pain or upset gets worse or lasts</li> <li>• redness or swelling is present in the painful area</li> <li>• any new symptoms appear</li> </ul>