

REVIEWED LABELING

Infant's Advil® Concentrated Drops: Carton

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

New/Revised Warnings	Previous Warnings
<p>Warnings Allergy alert: Ibuprofen may cause a severe allergic reaction which may include:</p> <ul style="list-style-type: none"> • hives • facial swelling • asthma (wheezing) • shock <p>Stomach bleeding warning: Taking more than recommended may cause stomach bleeding.</p>	<p>Warnings Allergy alert: Ibuprofen may cause a severe allergic reaction which may include:</p> <ul style="list-style-type: none"> • hives • facial swelling • asthma (wheezing) • shock
<p>Do not use if the child has ever had an allergic reaction to any other fever reducer/pain reliever</p>	<p>Do not use if the child has ever had an allergic reaction to any other fever reducer/pain reliever</p>
<p>Ask a doctor before use if the child has</p> <ul style="list-style-type: none"> • high blood pressure, heart or kidney disease or is taking a diuretic • not been drinking fluids • ulcers • bleeding problems • lost a lot of fluid due to continued vomiting or diarrhea • stomach problems that last or come back, such as heartburn, upset stomach or pain • problems or serious side effects from taking fever reducers or pain relievers 	<p>Ask a doctor before use if the child has</p> <ul style="list-style-type: none"> • not been drinking fluids • lost a lot of fluid due to continued vomiting or diarrhea • stomach pain • problems or serious side effects from taking fever reducers or pain relievers
<p>Ask a doctor or pharmacist before use if the child is</p> <ul style="list-style-type: none"> • under a doctor's care for any serious condition • taking any other product that contains ibuprofen, or any other pain reliever/fever reducer • taking a prescription product for anticoagulation (blood thinning) • taking any other drug 	<p>Ask a doctor or pharmacist before use if the child is</p> <ul style="list-style-type: none"> • under a doctor's care for any serious condition • taking any other drug • taking any other product that contains ibuprofen, or any other pain reliever/fever reducer
<p>When using this product give with food or milk if stomach upset occurs</p>	<p>When using this product give with food or milk if stomach upset occurs</p>
<p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> • an allergic reaction occurs. Seek medical help right away. • fever or pain gets worse or lasts more than 3 days • the child does not get any relief within first day (24 hours) of treatment • stomach pain or upset gets worse or lasts • redness or swelling is present in the painful area • any new symptoms appear 	<p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> • an allergic reaction occurs. Seek medical help right away. • fever or pain gets worse or lasts more than 3 days • the child does not get any relief within first day (24 hours) of treatment • stomach pain or upset gets worse or lasts • redness or swelling is present in the painful area • any new symptoms appear