



For immediate release
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**Pfizer, Inc. Issues A Voluntary Nationwide Recall Of One Lot Of
Children's Advil® Suspension Bubble Gum Flavored 4 FL OZ Bottle.**

New York, N.Y., August 27 - Pfizer Consumer Healthcare, a division of Pfizer Inc., is voluntarily recalling one lot of **Children's Advil® Suspension Bubble Gum Flavored 4 FL OZ Bottle** because of customer complaints that the dosage cup provided is marked in teaspoons and the instructions on the label are described in milliliters (mL).

Pfizer concluded that the use of the product with an unmatched dosage cup marked in teaspoons rather than milliliters has a chance of being associated with potential overdose. The most common symptoms associated with ibuprofen overdose include nausea, vomiting, headache, drowsiness, blurred vision and dizziness.

Children's Advil® Suspension Bubble Gum Flavored 4 FL OZ Bottle temporarily reduces fever, relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches.

Children's Advil® Suspension Bubble Gum Flavored 4 FL OZ Bottle, NDC 0573-0207-30, lot R51129 was distributed nationwide to wholesalers, distributors and retailers in the United States from May 2018 through June 2018.

Children's Advil® Suspension Bubble Gum Flavored 4 FL OZ Bottle
Lot and Packaging Information

NDC	Lot Number	Expiration Date	SKU	UPC	Configuration/Count
0573-0207-30	R51129	11/20	F00573020730	3-0573-0207-30-0	4 FL OZ (120 ml) bottle 36 bottles/case

Pfizer, Inc. places the utmost emphasis on patient safety and product quality at every step in the manufacturing and supply chain process.

Pfizer, Inc. has notified wholesalers, distributors and retailers to arrange for return of any recalled product. Wholesalers, distributors and retailers with an existing inventory of the lot being recalled, should stop use and distribution and quarantine the product immediately. Wholesalers, distributors and retailers that have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product from them. For instructions on returning product or additional assistance, call Stericycle at 1-800-805-3093 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday.

If consumers have questions regarding this recall or to report an adverse event, please contact the Pfizer Consumer Healthcare Information Line at 1-800-88-Advil (1-800-882-3845). Their hours of operation are Mon-Fri, 9am-5pm EST.

Consumers should contact their healthcare provider if they have experienced any problems that may be related to taking or using this drug product. Adverse reactions or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**:
www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form
www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall is being executed with the knowledge of the U.S. Food and Drug Administration.

The Bottle label is shown below:

Do Not Use if breakable ring on bottle cap is separated or missing.

Children's
Advil®
Suspension

Ibuprofen Oral Suspension
100 mg per 5 mL
Pain Reliever/Fever Reducer (NSAID)

Bubble Gum-Flavored Liquid
4 FL OZ (120 mL)

Active ingredient (in each 5 mL).....Ibuprofen 100 mg

Uses temporarily reduces fever, relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, blisters. If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if the child has had stomach ulcers or bleeding problems; takes a blood thinning (anticoagulant) or steroid drug; takes other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others), takes more or for a longer time than directed.

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Sore throat warning: Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult a doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by a doctor.

Do not use if the child has ever had an allergic reaction to any other fever reducer/pain reliever; right before or after heart surgery

Ask a doctor before use if stomach bleeding warning applies to the child; child has a history of stomach problems, such as heartburn; child has high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke; child has not been drinking fluids; child has lost a lot of fluid due to vomiting or diarrhea; child is taking a diuretic.

Ask a doctor or pharmacist before use if the child is under a doctor's care for any serious condition; taking any other drug

When using this product take with food or milk if upset stomach occurs

Stop use and ask a doctor if child experiences any of the following signs of stomach bleeding: feels faint, vomits blood, has bloody or black stools, or has stomach pain that does not get better; child has symptoms of heart problems or stroke: chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg swelling; the child does not get any relief within first day (24 hours) of treatment; fever or pain gets worse or lasts more than 3 days; redness or swelling is present in the painful area; any new symptoms appear

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Each 5 mL contains: **sodium 3 mg.** Store at 20-25°C (68-77°F).

Directions This product does not contain directions or complete warnings for adult use. Do not give more than directed. Shake well before using. mL = milliliter. Find right dose on chart. If possible, use weight to dose; otherwise use age. Repeat dose every 6-8 hours, if needed. Do not use more than 4 times a day. Measure only with the dosing cup provided. Dosing cup to be used with Children's Advil Suspension only. Do not use with other products. Dose lines account for product remaining in cup due to thickness of suspension.

Dosing Chart		
Weight (lb)	Age (yr)	Dose (mL)
under 24 lb	under 2 yr	ask a doctor
24-35 lb	2-3 yr	5 mL
36-47 lb	4-5 yr	7.5 mL
48-59 lb	6-8 yr	10 mL
60-71 lb	9-10 yr	12.5 mL
72-95 lb	11 yr	15 mL

Questions or comments? call 1-800-88-ADVIL
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For most recent product information, visit www.Advill.com PAA082590

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