

PAIN RELIEVER CHILDRENS- acetaminophen suspension
Safeway, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient (in each 5 mL)

Acetaminophen 160 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily reduces fever
- relieves minor aches and pains due to:
 - the common cold
 - flu
 - headache
 - sore throat
 - toothache

Warnings

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Liver warning: This product contains acetaminophen Severe liver damage may occur if your takes:

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or non prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if your child is allergic to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if your child has

liver disease.

Ask a doctor or pharmacist before use if your child is

taking the blood thinning drug warfarin.

When using this product,

do not exceed recommended dose (see overdose warning).

Stop use and ask a doctor if

- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days

These could be signs of a serious condition.

Keep out of reach of children.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical even if you do not notice any signs or symptoms.

Directions

- **this product does not contain directions or complete warnings for adult use**
- **do not take more than directed (see overdose warning)**
- **shake well before using**
- mL = milliliter
- find the right dose on chart below. If possible, use weight to dose, otherwise, use age
- use only the enclosed dosing cup designed for use with product. Do not use any other dosing device.
- If needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give more than 5 days unless directed by a doctor

Weight (lb)	Age (year)	Dose (mL or tsp)*
under 24	under 2	ask a doctor
24-35	2-3	5 mL

36-47	4-5	7.5 mL
48-59	6-8	10 mL
60-71	9-10	12.5 mL
72-95	11	15 mL

*or as directed by a doctor

Other information

- **each 5 mL contains:** sodium 2 mg
- store between 20-25°C (68-77°F).
- Do not refrigerate.
- see bottom panel for lot number and expiration date

Inactive ingredients

anhydrous citric acid, butylparaben, carboxymethylcellulose sodium, D&C red #33, FD&C red #40, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

Questions or comments?

Call **1-888-723-3929 Monday-Friday 7AM-6PM PST**

Principal Display Panel

FOR AGES 2-11 YEARS

Children's Pain Reliever

Acetaminophen 160 mg per 5 mL

Pain Reliever / Fever Reducer

Oral Suspension

- Aspirin free
- Alcohol free
- Ibuprofen free
- Dosing cup included

FL OZ (mL)

BUBBLE GUM FLAVOR

Compare to Children's Tylenol® Oral Suspension active ingredient**

**This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Tylenol® Oral Suspension.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING

DISTRIBUTED BY
 BETTER LIVING BRANDS LLC
 P.O. BOX 99, PLEASANTON, CA 94566-0009
 www.betterlivingbrandsLLC.com

Package Label

<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> use only the enclosed dosing cup designed for use with this product. Do not use any other dosing device. if needed, repeat dose every 4 hours while symptoms last do not give more than 5 times in 24 hours do not give more than 5 days unless directed by a doctor find the right dose on chart below. If possible, use weight to dose; otherwise, use age. <table border="1"> <thead> <tr> <th>Weight (lb)</th> <th>Age (year)</th> <th>Dose (mL)*</th> </tr> </thead> <tbody> <tr> <td>under 24</td> <td>under 2</td> <td>ask a doctor</td> </tr> <tr> <td>24-35</td> <td>2-3</td> <td>5 mL</td> </tr> <tr> <td>36-47</td> <td>4-5</td> <td>7.5 mL</td> </tr> <tr> <td>48-59</td> <td>6-8</td> <td>10 mL</td> </tr> <tr> <td>60-71</td> <td>9-10</td> <td>12.5 mL</td> </tr> <tr> <td>72-95</td> <td>11</td> <td>15 mL</td> </tr> </tbody> </table> <p>*or as directed by a doctor</p> <p>Other information</p> <ul style="list-style-type: none"> each 5 mL contains: sodium 2 mg store between 20-25°C (68-77°F) do not refrigerate see bottom panel for lot number and expiration date <p>Inactive ingredients butylparaben, carboxymethylcellulose sodium, citric acid, D&C red #33, FD&C red #40, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum</p> <p>Questions or comments? Call 1-877-753-3835 Monday-Friday 9AM-5PM EST</p>	Weight (lb)	Age (year)	Dose (mL)*	under 24	under 2	ask a doctor	24-35	2-3	5 mL	36-47	4-5	7.5 mL	48-59	6-8	10 mL	60-71	9-10	12.5 mL	72-95	11	15 mL	<p>Compare to Children's Tylenol® Oral Suspension active ingredient**</p> <p>NDC 21130-281-04</p>  <p>Children's Pain Reliever FOR AGES 2-11 YEARS Acetaminophen 160 mg per 5 mL Oral suspension</p> <p>BUBBLE GUM FLAVOR</p>  <ul style="list-style-type: none"> Alcohol Free Aspirin Free Ibuprofen Free Dosing cup included <p>4 FL OZ (118 mL)</p>	<p>Compare to Children's Tylenol® Oral Suspension active ingredient**</p> <p>NDC 21130-281-04</p>  <p>Children's Pain Reliever FOR AGES 2-11 YEARS Acetaminophen 160 mg per 5 mL Oral suspension</p> <p>BUBBLE GUM FLAVOR</p>  <ul style="list-style-type: none"> Alcohol Free Aspirin Free Ibuprofen Free Dosing cup included <p>4 FL OZ (118 mL)</p>	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredient (in each 5 mL)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Acetaminophen 160 mg</td> <td>Pain reliever/fever reducer</td> </tr> </tbody> </table> <p>Uses</p> <ul style="list-style-type: none"> temporarily reduces fever temporarily relieves minor aches and pains due to <ul style="list-style-type: none"> the common cold flu headache sore throat toothache <p>Warnings</p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes:</p> <ul style="list-style-type: none"> more than 5 doses in 24 hours, which is the maximum daily amount with other drugs containing acetaminophen <p>Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: skin reddening, blisters, rash. If a skin reaction occurs, stop use and seek medical help right away.</p> <p>Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.</p> <p>Do not use</p> <ul style="list-style-type: none"> with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. if your child is allergic to acetaminophen or any of the inactive ingredients in this product <p>Ask a doctor before use if your child has liver disease.</p> <p>Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin.</p> <p>When using this product, do not exceed recommended dose (see Overdose warning).</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> new symptoms occur redness or swelling is present pain gets worse or lasts more than 5 days fever gets worse or lasts more than 3 days <p>These could be signs of a serious condition.</p> <p>Keep out of reach of children.</p> <p>Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical even if you do not notice any signs or symptoms.</p> <p>Directions</p> <ul style="list-style-type: none"> this product does not contain directions or complete warnings for adult use do not take more than directed (see Overdose warning) shake well before using mL = milliliter 	Active ingredient (in each 5 mL)	Purpose	Acetaminophen 160 mg	Pain reliever/fever reducer
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<p>DISTRIBUTED BY BETTER LIVING BRANDS LLC P.O. BOX 99, PLEASANTON, CA 94566-0009 1-888-723-3829 www.betterlivingbrandsLLC.com</p>  <p>Scan here for more information</p> <p>OUR PROMISE QUALITY & SATISFACTION 100% GUARANTEED OR YOUR MONEY BACK.</p>			<p>TRAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.</p>	<p>SS967 RD20046</p>  <p>3 21130 78781 5</p> <p>PLD-0230D FC006638</p> <p>Lot No.: Exp. Date:</p>																								

SIGNATURE CARE Children's Pain Reliever Bubble Gum Flavor

PAIN RELIEVER CHILDRENS
 acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-281
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-281-04	1 in 1 BOX	06/30/2015	06/30/2025
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	06/30/2015	06/30/2025

