

PAIN RELIEVER- acetaminophen suspension
P & L Development, LLC

Drug Facts

Active ingredient (in each 5 mL)

Acetaminophen 160 mg

Purpose

Pain reliever/fever reducer

Uses

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

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

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

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.

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 (1-800-222-1222) right away. 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
- 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.

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

*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 blue #1, flavor, glycerin, high fructose corn syrup, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

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

Children's Pain reliever

Acetaminophen 160 mg per 5 mL

Oral suspension

Pain reliever/Fever reducer

- alcohol free
- aspirin free
- ibuprofen free

For ages 2 - 11 years

FL OZ (mL)


GRAPE FLAVOR

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

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

Distributed by: **PL Developments**
 200 Hicks Street, Westbury, NY 11590

Product Label



Compare to the active ingredient in Children's Tylenol® Oral Suspension**
 NDC 49580-2880-4


children's
 pain relief

Acetaminophen
 160 mg per 5 mL

Oral Suspension

pain reliever/
 fever reducer

for ages 2-11 years
 alcohol free
 aspirin free
 ibuprofen free

grape flavor

4 fl oz (118 mL)

Drug Facts

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Acetaminophen 160 mg.....	Pain reliever/fever reducer


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

Warnings
Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes: ■ more than 5 doses in 24 hours, which is the maximum daily amount ■ with other drugs containing acetaminophen. **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. **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 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


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



Manufactured by:
PL Developments
 11865 S. Alameda St
 Lynwood, CA 90262

PLD-A2370 LB009737



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Drug Facts (continued)

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).

Drug Facts (continued under label) PEEL HERE →

Drug Facts (continued)

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Drug Facts (continued)

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Inactive ingredients butylparaben, carboxymethylcellulose sodium, citric acid, D&C red #33, FD&C blue #1, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

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READYinCASE Children's Pain Reliever Grape Flavor

PAIN RELIEVER

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49580-2880
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	Score
Shape	Size
Flavor	Imprint Code
GRAPE	
Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49580-2880-4	1 in 1 BOX	03/15/2024	
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	03/15/2024	

Labeler - P & L Development, LLC (101896231)