

PAIN RELIEF INFANTS- acetaminophen suspension
P & L Development, LLC

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
- 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 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
- only use the enclosed syringe.

Do not use any other syringe, dropper, spoon or dosing device when giving this medicine to your child.

- remove cap and insert syringe into hole at top of bottle and turn upside down.
- pull back syringe until filled to the prescribed level. if you pass the prescribed level, simply push syringe back until you have reached the desired level. Slowly dispense the liquid into your child's mouth (towards inner cheek).
- if needed, repeat dose every 4 hours while symptoms last.
- do not use give more than 5 times in 24 hours
- do not give more than 5 days unless directed by a doctor
- replace cap tightly to maintain child resistance

- 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

*or as directed by a doctor

Other information

- 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, flavors, 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 Infants' Tylenol® Oral Suspension**

Infants' Pain Relief

Acetaminophen 160 mg per 5 mL

oral suspension

pain reliever / fever reducer

for ages 2-3 years

alcohol free

aspirin free

ibuprofen free

FL OZ (mL)

Use Only Enclosed Syringe

Grape flavor

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

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

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

Package Label

Drug Facts

Active ingredient (in each 5 mL) **Purpose**
 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

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 Overtose 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.
Overtose warning: Taking more than the recommended dose (overtose) may cause liver damage. In case of overtose, 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 Overtose warning)
 ■ shake well before using

Drug Facts (continued)

■ mL = milliliter
 ■ only use the enclosed syringe.
Do not use any other syringe, dropper, spoon or dosing device when giving this medicine to your child.
 ■ remove cap and insert syringe into hole at top of bottle and turn upside down
 ■ pull back syringe until filled to the prescribed level. If you pass the prescribed level, simply push syringe back until you have reached the desired level. Slowly dispense the liquid into your child's mouth (towards inner cheek).
 ■ 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
 ■ replace cap tightly to maintain child resistance
 ■ 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

*or as directed by a doctor

Other information
 ■ store between 20-25°C (68-77°F)
 ■ do not refrigerate
 ■ see bottom panel for lot number and expiration date

Inactive ingredients butylparaben, carbocymethylcellulose 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

Questions or comments? Call 1-877-753-3635 Monday-Friday 9AM-5PM EST

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



Compare to the active ingredient in **Infants' Tylenol® Oral Suspension****
 NDC 49580-0324-2

infants' pain relief
Acetaminophen 160 mg per 5 mL
 oral suspension
 pain reliever/fever reducer




for ages 2-3 years
 alcohol free
 aspirin free
 ibuprofen free
2 fl oz (59 mL)
 grape flavor
 use only enclosed syringe

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

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

PLD-0271D FC005581



ReadyinCase Infants' Pain Relief Grape Liquid

PAIN RELIEF INFANTS			
acetaminophen suspension			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49580-0324
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)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
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)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49580-0324-2	1 in 1 BOX	04/30/2016	04/30/2025
1		59 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 not final	part343	04/30/2016	04/30/2025

Labeler - P & L Development, LLC (101896231)

