

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, insert syringe into hole at top of bottle until it snaps into place and turn upside down
- pull back syringe until filled to be prescribed level. If you pass the prescribed level, invert assembly to right side up on flat surface and 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

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, carboxymethylcellulose sodium, citric acid, 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 and Fever

Acetaminophen 160 mg per 5 mL

oral suspension

pain reliever / fever reducer

dye free

for ages 2-3 years

alcohol free

aspirin free

ibuprofen free

Cherry flavor

Use only enclosed syringe

FL OZ (mL)

**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 IF PRINTED SAFETY SEAL AROUND BOTTLE IS BROKEN OR MISSING.

Manufactured by:

PL Developments

11865 S Alameda St

Lynwood, CA 90262

Package Label

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Acetaminophen 160 mg	Pain reliever/fever reducer

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 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 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.

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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

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 butyrosorb, carbomethylcellulose sodium, citric acid, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

Questions or comments? Call 1-877-753-3636 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 49580-0322-2

infants' pain relief

Acetaminophen 160 mg per 5 mL

oral suspension

pain reliever/fever reducer

dye free

for ages 2-3 years
alcohol free
aspirin free
ibuprofen free

2 fl oz (59 mL)

cherry 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-42680 FC000550

3 49580 32202 8

ReadyinCase Infants Pain Relief Cherry Liquid

PAIN RELIEF INFANTS

acetaminophen suspension

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:49580-0322

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)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49580-0322-2	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)

