

## **CHILDRENS PAIN RELIEF READYINCASE- 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**

**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 child 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 dosage (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**
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- use only enclosed dosing cup designed for use with this product. Do not use any other dosing device.
- mL = milliliter
- 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 (tsp or 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

### 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

butylparaben, carboxymethylcellulose sodium, microcrystalline cellulose, citric acid, D&C red 33, FD&C blue 1, flavors, glycerin, high fructose corn syrup, 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 Relief

Acetaminophen 160 mg per 5 mL

oral suspension

pain reliever/fever reducer

for ages 2 to 11 years

alcohol free

aspirin free

ibuprofen free

FL OZ (mL)

grape flavor

\*\*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.**

Manufacture by:

PL Developments

11865 S. Alameda St  
Lynwood, CA 90262

Product Label

**Drug Facts (continued)**

- 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** 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

**Questions or comments?**  
Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

\*\*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.**

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

**ready in case**

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

NDC 49580-0288-4

**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

4 FL OZ (118 mL)

grape flavor

**ready in case**

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

NDC 49580-0288-4

**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

4 FL OZ (118 mL)

grape flavor

**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 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

  
3 49580 28804 1

PLD-G237D FC004034

Lot No.:  
Exp. Date:

READYinCASE Children's Pain Relief

CHILDRENS PAIN RELIEF READYINCASE

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49580-0288
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 BLUE NO. 1 (UNII: H3R47K3TBD)				
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	GRAPE	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49580-0288-4	1 in 1 BOX	11/30/2014	11/30/2025
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 not final	part343		11/30/2014	11/30/2025

**Labeler** - P & L Development, LLC (101896231)

