

# **INFANTS PAIN AND FEVER- acetaminophen suspension**

## **Kroger Company**

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### **Kroger Co. Infants' Pain & Fever 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**

**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 has ever had an allergic reaction to this product or any of its ingredients

**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**

- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present. These could be signs of a serious condition.

**Keep out of reach of children.**

**Overdose warning:** 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 give more than directed (see overdose warning)**
- **shake well before using**
- mL = milliliter
- find right dose on chart. If possible, use weight to dose; otherwise, use age.
- push air out of syringe. Insert syringe tip into bottle opening.
- flip bottle upside down. Pull yellow part of syringe to the first dose line and then push product back into bottle.
- pull yellow part of syringe until it reaches and stays at the correct dose
- dispense liquid slowly into child’s mouth, toward inner cheek
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- replace cap tightly to maintain child resistance

**Dosing Chart**

<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Dose (mL)*</b>
under 24	under 2 years	ask a doctor

24-35	2-3 years	5 mL
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\* or as directed by a doctor

**Attention:** use only enclosed syringe specifically designed for use with this product. Do not use any other dosing device.

### **Other information**

- store at 20-25°C (68-77°F)
- **do not use if printed neckband is broken or missing**

### **Inactive ingredients**

anhydrous citric acid, calcium sulfate, carrageenan, flavor, glycerin, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, tribasic sodium phosphate

### **Questions or comments?**

**1-800-632-6900**

### **Package/Label Principal Display Panel**

COMPARE TO the active ingredient of INFANTS' TYLENOL® ORAL SUSPENSION

See side panel

Kroger®

OUR PHARMACIST RECOMMENDED

Age 2-3 Years

infants' Pain & Fever

Acetaminophen 160 mg per 5 mL

Pain Reliever / Fever Reducer

Suspension Liquid

Pediatrician Preferred Dosing System

Alcohol Free

Aspirin Free

Ibuprofen Free

No High Fructose Corn Syrup

DYE-FREE

Grape Flavor

Use only with enclosed syringe.  
 See side panel for more information.  
 2 FL OZ (59 mL)

**Drug Facts**

**Active ingredient (in each 5 mL)**    **Purpose**  
 Acetaminophen 160 mg.....Pain reliever/fever reducer

**Uses** temporarily:    ■ reduces fever  
 ■ 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 has ever had an allergic reaction to this product or any of its ingredients  
**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  
 ■ pain gets worse or lasts more than 5 days  
 ■ fever gets worse or lasts more than 3 days  
 ■ redness or swelling is present. These could be signs of a serious condition.  
**Keep out of reach of children.**  
**Overdose warning:** 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 give more than directed (see overdose warning)  
 ■ shake well before using    ■ mL = milliliter  
 ■ find right dose on chart. If possible, use weight to dose; otherwise, use age.  
 ■ push air out of syringe. Insert syringe tip into bottle opening.  
 ■ flip bottle upside down. Pull yellow part of syringe to the first dose line and then push product back into bottle. ▶

**Drug Facts (continued)**

■ pull yellow part of syringe until it reaches and stays at the correct dose  
 ■ dispense liquid slowly into child's mouth, toward inner cheek  
 ■ repeat dose every 4 hours while symptoms last  
 ■ do not give more than 5 times in 24 hours  
 ■ replace cap tightly to maintain child resistance

**Dosing Chart**

Weight (lb)	Age (yr)	Dose (mL)**
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 mL

\*\* or as directed by a doctor  
**Attention:** use only enclosed syringe specifically designed for use with this product. Do not use any other dosing device.

**Other information**  
 ■ store at 20-25°C (68-77°F)  
 ■ do not use if printed neckband is broken or missing

**Inactive ingredients** anhydrous citric acid, calcium sulfate, carrageenan, flavor, glycerin, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucrose, tribasic sodium phosphate

**Questions or comments?**  
 1-800-632-6900

\*\*Tylenol® is a registered trademark of Johnson & Johnson Corporation, New Brunswick, NJ 08933. Johnson & Johnson Corporation is not affiliated with The Kroger Co. or this product.

**DISTRIBUTED BY**  
**THE KROGER CO.**  
 CINCINNATI, OHIO 45202  
**QUALITY GUARANTEE**  
 800-632-6900  
 www.kroger.com

**GLUTEN FREE**    **PLEASE RECYCLE**

**Kroger** Age 2-3 Years

**infants'**  
**Pain & Fever**

Acetaminophen  
 160 mg per 5 mL  
 Pain Reliever/  
 Fever Reducer  
 Suspension Liquid

**DYE-FREE Grape Flavor**

NDC 30142-766-16

**Kroger**

Age 2-3 Years

**infants'**  
**Pain & Fever**

Acetaminophen  
 160 mg per 5 mL  
 Pain Reliever/  
 Fever Reducer  
 Suspension Liquid

Pediatric Preferred  
 Dosing System

Alcohol Free  
 Aspirin Free  
 Ibuprofen Free  
 No High Fructose  
 Corn Syrup

**DYE-FREE Grape Flavor**

Use only with enclosed syringe. See side panel for more information.

**2 FL OZ (59 mL)**

0 41260 01890 9

76616 45 C7

**IMPORTANT:**  
 Please see dosing chart or ask a doctor for your child's correct dose.

**STEP 1.** See *Directions* for the correct dose for your child.  
**STEP 2.** Shake well before using.  
**STEP 3.** Push air out of syringe. Insert syringe tip into bottle opening.

**STEP 4.** Flip bottle upside down. Pull yellow part of syringe to the first dose line and then push product back into bottle.  
**STEP 5.** Pull yellow part of syringe until it reaches and stays at the correct dose.

**STEP 6.** Dispense liquid slowly into child's mouth.

## INFANTS PAIN AND FEVER

acetaminophen suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:30142-766
<b>Route of Administration</b>	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)	
CALCIUM SULFATE, UNSPECIFIED FORM (UNII: WAT0DDB505)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TGW28D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-766-16	1 in 1 CARTON	03/15/2012	
1		59 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 Drug	M013	03/15/2012	

**Labeler** - Kroger Company (006999528)

Revised: 8/2024

Kroger Company