

PAIN AND FEVER INFANTS- acetaminophen suspension

Kroger Company

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.

Kroger Co. Pain & Fever Drug Facts

Active ingredient (in each 5 mL)

Acetaminophen 160 mg

Purposes

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

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: Taking more than the recommended dose (overdose) may cause liver damage. 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. Firmly push syringe into bottle opening.
- turn bottle upside down. Pull syringe to the first dose line and then push product back into bottle.
- pull 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 bottle neckband is broken or missing

Inactive ingredients

anhydrous citric acid, butylparaben, calcium sulfate, carrageenan, D&C red #33, FD&C blue #1, flavor, glycerin, high fructose corn syrup, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, 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

SEE NEW DOSAGE & DIRECTIONS

Infants' Pain & Fever

Acetaminophen

Pain Reliever / Fever Reducer

Suspension Liquid

See side panel for more information

Pediatrician Preferred Dosing System

Use Only with Enclosed Syringe

Alcohol Free

Aspirin Free

Ibuprofen Free

Grape Flavor

2 FL OZ (59 mL)

160 mg per 5 mL



FROM OUR FAMILY TO YOURS

Infants' Pain & Fever

Acetaminophen
Pain Reliever/Fever Reducer
Suspension Liquid

COMPARE TO the active ingredient of INFANTS' TYLENOL® ORAL SUSPENSION **See side panel

SEE NEW DOSAGE & DIRECTIONS

NDC 30142-946-16



FROM OUR FAMILY TO YOURS



Infants' Pain & Fever

Acetaminophen
Pain Reliever/Fever Reducer
Suspension Liquid

See side panel for more information

- Pediatrician Preferred Dosing System
- Use Only with Enclosed Syringe
- Alcohol Free
- Aspirin Free
- Ibuprofen Free



Grape Flavor

2 FL OZ (59 mL)



STEP 1. See *Directions* for the correct dose for your child.

STEP 2. Shake well before using.

STEP 3. Push air out of syringe. Firmly push syringe into bottle opening.



STEP 4. Turn the bottle upside down. Pull syringe to the first dose line and then push product back into bottle.

STEP 5. Pull syringe until it reaches and stays at the correct dose.



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

IMPORTANT:

New Dosage and Directions. Please see dosing chart or ask a doctor for your child's correct dose.

160 mg per 5 mL

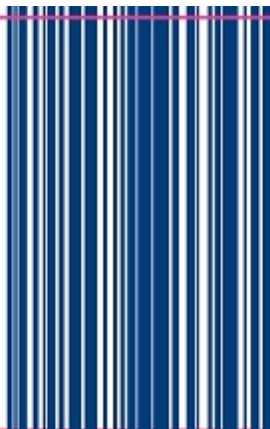


0 41260 35832 6

LOT NO.

EXP.

: 94616 45 C3



Drug Facts

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

Uses temporarily:

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■ relieves minor aches and pains due to:	■ flu
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■ toothache	

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Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin

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Drug Facts (continued)

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Questions or comments?

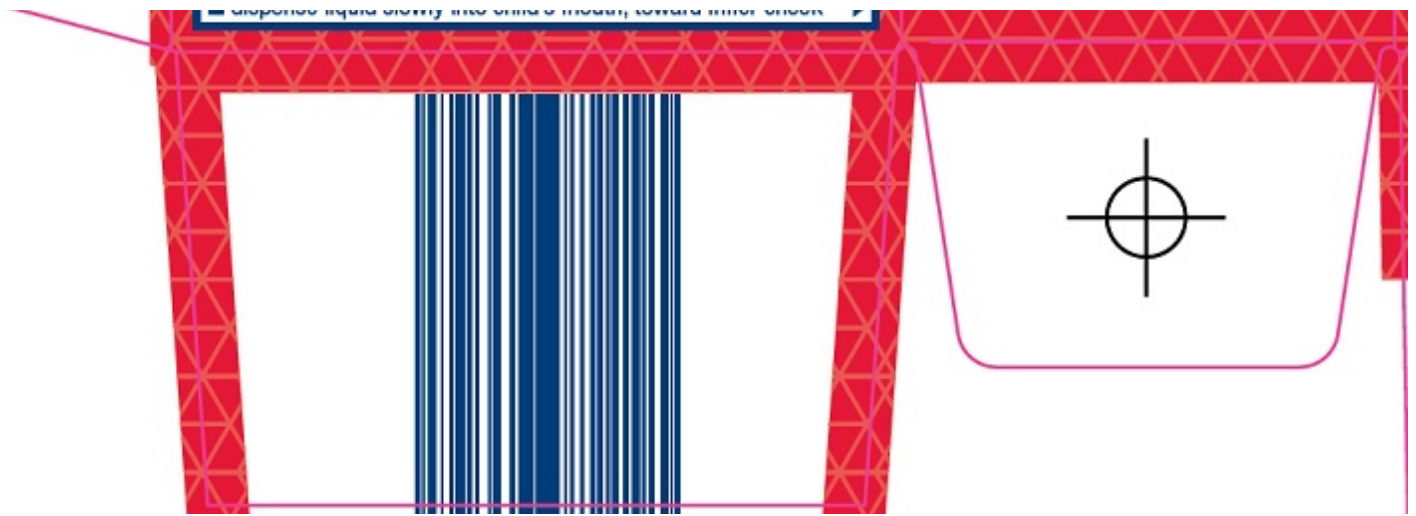
1-800-632-6900

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GLUTEN FREE



PAIN AND FEVER INFANTS

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-946
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: 3QPII03FV8)	
CALCIUM SULFATE (UNII: WAT0DDB505)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X)	

Product Characteristics

Color	PURPLE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30 142-946-16	1 in 1 CARTON		
1		59 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	09/20/2011	

Labeler - Kroger Company (006999528)

Revised: 3/2014

Kroger Company