

PAIN AND FEVER RELIEF INFANTS- acetaminophen suspension
Dolgenercorp, Inc. (DOLLAR GENERAL & REXALL)

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:
 - flu
 - the common cold
 - 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 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 the recommended dose (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 (yr)	Dose (mL)
under 24	under 2 years	ask a doctor
24-35	2-3 years	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

acesulfame potassium, anhydrous citric acid, butylparaben, carboxymethylcellulose sodium, FD&c red #40, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol, xanthan gum

Questions or comments?

Call **1-888-309-9030**

Principal Display Panel

Compare to active ingredient of Infants' Tylenol® Oral Suspension**

For Ages 2 to 3 Years

Infants'

Pain & Fever Relief

Acetaminophen

160 mg per 5 mL

Oral suspension

Pain Reliever / Fever Reducer

- Alcohol free
- Aspirin free
- Ibuprofen free

Enhanced dosing system reduces the chance of accidental ingestion and overdose

Use only enclosed syringe

FL OZ (mL)

CHERRY 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 THE BOTTLE IS BROKEN OR MISSING.

DISTRIBUTED BY DOLGENCORP, LLC

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

Package Label

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

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, insert syringe into hole at top of bottle until it snaps into place and turn upside down
■ pull back syringe until filled to the 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

*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 acetamide, potassium, butylparaben, carbomethylcellulose, sodium, citric acid, FD&C red #40, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol, xanthan gum.
Questions or comments?
Call 1-888-309-9030

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

Compare to active ingredient of Infants' Tylenol® Oral Suspension**

For Ages 2 to 3 Years
Infants' Pain & Fever Relief
Acetaminophen 160 mg per 5 mL Oral Suspension
Pain Reliever/Fever Reducer
• Alcohol free
• Aspirin free
• Ibuprofen free
Enhanced Dosing System Reduces the Chance of Accidental Ingestion and Overdose.
Use Only Enclosed Syringe
2 FL OZ (59 mL)
160mg PER 5 mL
Cherry Flavor

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR PRINTED SAFETY SEAL AROUND THE BOTTLE IS BROKEN OR MISSING.
KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

100% Satisfaction Guaranteed!
(888) 309-9030

DISTRIBUTED BY DOLGENCORP, LLC
100 MISSION RIDGE
GOODLETTSVILLE, TN 37072

PLD-E2680 FC003987



Lot No.:

Exp. Date:

DOLLAR GENERAL HEALTH Pain & Fever Relief Cherry Flavor

PAIN AND FEVER RELIEF INFANTS

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-021	
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)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
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)				
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
Product Characteristics				
Color		Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-021-02	1 in 1 BOX	04/30/2015	04/30/2025
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 not final	part343		04/30/2015	04/30/2025

Revised: 1/2023

Dolgencorp, Inc. (DOLLAR GENERAL & REXALL)