DG HEALTH INFANTS PAIN AND FEVER- acetaminophen suspension Dolgencorp Inc

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.

Dolgencorp, LLC 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			
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 wrap is broken or missing

Inactive ingredients

anhydrous citric acid, butylparaben, calcium sulfate, carrageenan, FD&C red #40, 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?

1-888-309-9030

Package/Label Principal Display Panel

SEE NEW WARNINGS

Compare to active ingredient of Infants' Tylenol® Oral Suspension

For Ages 2 to 3 Years

Infants'

Pain & Fever

Acetaminophen 160 mg per 5 mL

Pain Reliever / Fever Reducer

Suspension Liquid

Alcohol free

Aspirin free

Ibuprofen free

Pediatrician Preferred Dosing System

Use only with enclosed syringe.

See side panel for more information.

Cherry Flavor

1 FL OZ (30mL)

160 mg PER 5 mL





DG™health

SEE NEW WARNINGS

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

For Ages 2 to 3 Years

Infants'

Pain & Fever

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

- Alcohol free
- Aspirin free
- Ibuprofen free

Pediatrician Preferred Dosing System

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



Cherry Flavor

1 FL OZ (30mL)

160mg PER 5mL

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.





Pain Reliever/ Fever Reducer Acetaminophen 160 mg per 5 mL

Pain & Fever

For Ages 2 to 3 Years

DG Pealth

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

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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.

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Drug Facts (continued)

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Other information

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- do not use if printed bottle wrap is broken or missing

Inactive ingredients anhydrous citric acid, butylparaben, calcium sulfate, carrageenan, FD&C red #40. 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? 1-888-309-9030

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

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

and then push product back into bottle.

100% Satisfaction Guaranteed! (888) 309-9030



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LOT NO.

EXP.

: 16110 VT C4

DG HEALTH INFANTS PAIN AND FEVER

acetaminophen suspension

Product 1	Information
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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:55910-161

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D)ACETAMINO PHEN160 mg in 5 mL

Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
BUTYLPARABEN (UNII: 3QPI1U3FV8)		
CALCIUM SULFATE (UNII: WAT0 DDB505)		

CARRAGEENAN (UNII: 5C69 YCD2YJ)

FD&C RED NO. 40 (UNII: WZB9127XOA)

GLYCERIN (UNII: PDC6A3C0OX)

Inactive Ingredients

HIGH FRUCTO SE CORN SYRUP (UNII: XY6 UN3QB6S)

CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)

CARBO XYMETHYLCELLULO SE SODIUM (UNII: K679 OBS 311)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

WATER (UNII: 059QF0KO0R)

SODIUM BENZOATE (UNII: OJ245FE5EU)

SORBITOL (UNII: 506T60A25R)

SODIUM PHO SPHATE, TRIBASIC (UNII: A752Q30 A6 X)

Product Characteristics				
Color	RED	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

	Packaging						
l	# Item Co	le	Package Description	Marketing Start Date	Marketing End Date		
ı	1 NDC:55910-1	51-10	1 in 1 CARTON	05/03/2012			
ı	1		30 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	05/03/2012		

Labeler - Dolgencorp Inc (068331990)

Revised: 12/2018 Dolgencorp Inc