

INFANTS PAIN RELIEF- acetaminophen suspension
AmerisourceBergen (Good Neighbor Pharmacy) 46122

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

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 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 directed (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 (year)	Dose (mL)
under 24	under 2	ask a doctor
24-35	2-3	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

butylparaben, carboxymethylcellulose, citric acid, 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**

Principal Display Panel

For ages 2-3 years

****Compare to the active ingredient in Infants' Tylenol® Oral Suspension**

Infants' Pain and Fever

Acetaminophen 160 mg per 5 mL

- pain reliever/fever reducer
- alcohol free
- aspirin free
- ibuprofen free

Cherry flavor

Use only enclosed syringe

Oral suspension

FL OZ (mL)

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF PRINTED SAFETY SEAL AROUND BOTTLE IS BROKEN OR MISSING.

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

Package Label

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 ■ hives ■ 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

Drug Facts (continued)

■ 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 and insert syringe into hole at top of bottle and turn upside down
 ■ pull back syringe until filled to the prescribed level. If you pass the prescribed level, 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
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 ■ 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
 butylparaben, carbonylmethylcellulose sodium, citric acid, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

Questions or comments? Call 1-877-753-3835 Monday-Friday 9AM-5PM EST

NDC 46122-340-46

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



FOR AGES 2-3 YEARS

Infants' Pain Relief

Oral Suspension

Dye-Free Cherry Flavor

**Acetaminophen
 160 mg per 5 mL
 Pain Reliever/Fever Reducer**

- Alcohol Free
- Aspirin Free
- Ibuprofen Free

Use Only
 Enclosed Syringe

2 fl oz (59 mL)



TAMPER EVIDENT: DO NOT USE IF CARTON IS
 OPENED OR PRINTED SAFETY SEAL AROUND
 THE BOTTLE IS BROKEN OR MISSING.



Distributed By
 AmerisourceBergen
 1300 Morris Drive
 Chesterbrook, PA 19087
 Questions or Concerns?
 Visit us at www.mygnp.com

P.D.-02690 F003108



Infant's Pain relief

INFANTS PAIN RELIEF

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-340
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: 3QP1IU3FV8)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
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)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
Product Characteristics				
Color		Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46122-340-46	1 in 1 BOX	01/14/2016	12/31/2022
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	01/14/2016	12/31/2022	

Labeler - AmerisourceBergen (Good Neighbor Pharmacy) 46122 (007914906)

Registrant - P & L Development, LLC (079765031)