

INFANTS PAIN AND FEVER - acetaminophen suspension

Aurohealth LLC

Drug Facts

Active ingredient (in each 5 mL)

Acetaminophen, USP 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 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 using 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 for adults as well as for children 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.
- use only enclosed syringe designed for use with this product. Do not use any other dosing device.
- remove bottle cap and insert syringe tip through opening at top of the bottle
- tip bottle upside down and draw medicine into the syringe
- fill to dose level
- 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 lbs	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

- **each 5 mL contains:** sodium 6 mg
- store at 20° to 25°C (68° to 77°F)
- **do not use if shrink sleeves is broken or missing**

Inactive ingredients

butylparaben, carboxymethylcellulose sodium, citric acid anhydrous, flavor, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, noncrystallizing sorbitol solution, propylene glycol, purified water, sodium benzoate, sucralose, xanthan gum

Questions or comments?

1-855-274-4122

Distributed by:

AUROHEALTH LLC.

279 Princeton-Hightstown Road,

East Windsor, NJ 08520

Made in India

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 2 FL OZ (60 mL) Container Label

AUROHEALTH

NDC 58602-169-11

INFANTS' PAIN & FEVER

Suspension Liquid

Acetaminophen Oral Suspension

160 mg per 5 mL

Pain Reliever & Fever Reducer

Alcohol, Aspirin, Ibuprofen

& Gluten Free

Dye-Free Grape Flavor
Use ONLY enclosed syringe
2 FL OZ (60 mL)

Top Layer Printing side

<p>AUROHEALTH NDC 58602-169-11</p> <p>INFANTS' PAIN & FEVER</p> <p>Suspension Liquid</p> <p>Acetaminophen Oral Suspension 160 mg per 5 mL</p> <p>Pain Reliever & Fever Reducer Alcohol, Aspirin, Ibuprofen & Gluten Free</p> <p>Dye-Free Grape Flavor</p> <p>Use ONLY enclosed syringe</p> <p>2 FL OZ (60 mL)</p>	<p>Drug Facts</p> <p>Active ingredient (in each 5 mL)</p> <p>Acetaminophen, USP 160 mg.....Pain reliever/fever reducer</p> <p>Purpose</p> <p>Uses temporarily:</p> <ul style="list-style-type: none"> reduces fever relieves minor aches and pains due to: <ul style="list-style-type: none"> the common cold flu headache sore throat toothache <p>Warnings</p> <p>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</p>	<p>DO NOT USE IF SHRINK SLEEVES IS BROKEN OR MISSING</p> <p>Distributed by: AUROHEALTH LLC. 279 Princeton-Hightstown Road, East Windsor, NJ 08520</p> <p>Made in India</p> <p>P1436495</p> <p>* Unvarnished Zone (dotted line not for printing) 35 x 13 mm</p> <p>Lift Here For Drug Facts</p>
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Top Layer Adhesive side

Drug Facts (continued)

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** 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 for adults as well as for children 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. use only enclosed syringe designed for use with this product. Do not use any other dosing device. remove bottle cap and insert syringe tip through opening at top of the bottle tip bottle upside down and draw medicine into the syringe fill to dose level 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

P1436495

Base layer

Drug Facts (continued)

Dosing Chart

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Attention: use only enclosed syringe specifically designed for use with this product. Do not use any other dosing device. **Other information** ■ each 5 mL contains: sodium 6 mg ■ store at 20° to 25°C (68° to 77°F) **Inactive ingredients** butylparaben, carboxymethylcellulose sodium, citric acid anhydrous, flavor, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, noncrystallizing sorbitol solution, propylene glycol, purified water, sodium benzoate, sucralose, xanthan gum **Questions or comments?** © 1-855-274-4122

P1436495

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 2 FL OZ (60 mL) Carton Label

NDC 58602-169-11

***Compare to Infants'*

TYLENOL® Oral Suspension

active ingredient

AUROHEALTH

INFANTS'

PAIN & FEVER

Suspension Liquid

Acetaminophen Oral Suspension 160 mg per 5 mL

Pain Reliever & Fever Reducer

Alcohol Free

Aspirin Free

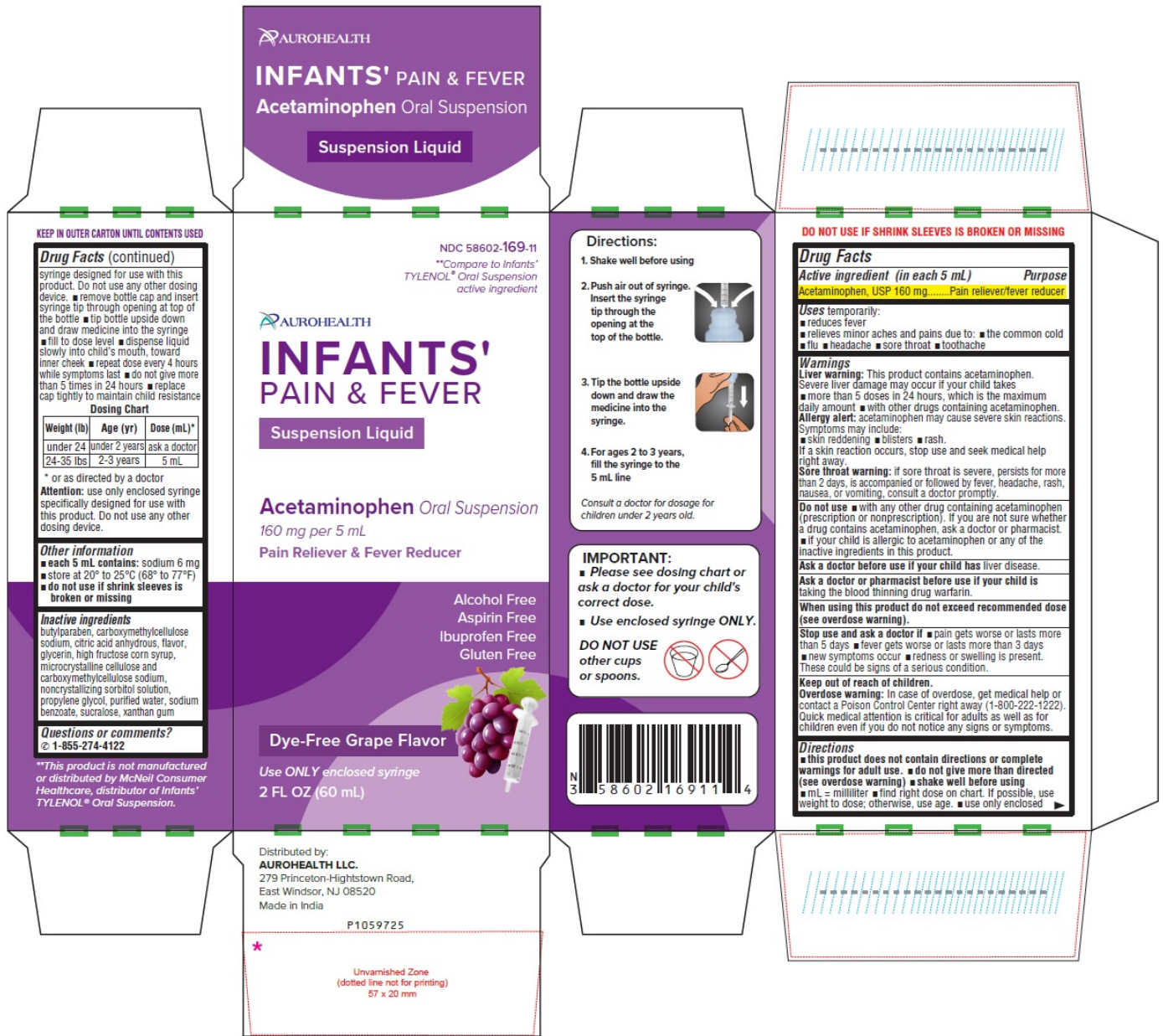
Ibuprofen Free

Gluten Free

Dye-Free Grape Flavor

Use ONLY enclosed syringe

2 FL OZ (60 mL)



INFANTS PAIN AND FEVER

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-169
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, UNSPECIFIED FORM (UNII: K679OBS311)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GRAPE (UNII: 6X543N684K)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
NONCRYSTALLIZING SORBITOL SOLUTION (UNII: 9E0S3UM200)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	WHITE (White to off-white)	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-169-11	1 in 1 CARTON	03/20/2026	
1		60 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	03/20/2026	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(58602-169) , MANUFACTURE(58602-169)

Revised: 3/2026

Aurohealth LLC