

# **INFANTS PAIN AND FEVER - acetaminophen suspension**

## **Aurohealth LLC**

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### ***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 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

## 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 58602-168-11

**INFANTS' PAIN & FEVER**

Suspension Liquid

**Acetaminophen** Oral Suspension

**160 mg per 5 mL**

**Pain Reliever & Fever Reducer**

Alcohol, Aspirin, Ibuprofen

& Gluten Free

Dye-Free Cherry Flavor  
Use **ONLY** enclosed syringe

**2 FL OZ (60 mL)**

### Top Layer Printing side

<p><b>AUROHEALTH</b> NDC 58602-168-11</p> <p><b>INFANTS' PAIN &amp; FEVER</b></p> <p>Suspension Liquid</p> <p><b>Acetaminophen</b> Oral Suspension 160 mg per 5 mL</p> <p>Pain Reliever &amp; Fever Reducer Alcohol, Aspirin, Ibuprofen &amp; Gluten Free</p> <p>Dye-Free Cherry Flavor</p> <p>Use <b>ONLY</b> enclosed syringe</p> <p><b>2 FL OZ (60 mL)</b></p>	<p><b>Drug Facts</b> <i>Active ingredient (in each 5 mL)</i></p> <p>Acetaminophen, USP 160 mg.....Pain reliever/fever reducer</p> <p><i>Purpose</i></p> <p><b>Uses</b> temporarily:</p> <ul style="list-style-type: none"> <li>■ reduces fever</li> <li>■ relieves minor aches and pains due to: ■ the common cold ■ flu</li> <li>■ headache ■ sore throat ■ toothache</li> </ul> <p><b>Warnings</b></p> <p><b>Liver warning:</b> 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. <b>Allergy alert:</b> 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. <b>Sore throat warning:</b> if sore throat is severe, persists for more than 2 days, is accompanied or followed by</p>	<p><b>DO NOT USE IF SHRINK SLEEVES IS BROKEN OR MISSING</b></p> <p>Distributed by: <b>AUROHEALTH LLC.</b> 279 Princeton-Hightstown Road, East Windsor, NJ 08520</p> <p>Made in India</p> <p>P1436494</p> <p>* Unvarnished Zone (dotted line not for printing) 35 x 13 mm</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

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### Base layer

**Drug Facts (continued)**

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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

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

**NDC 58602-168-11**

**\*\*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 Cherry Flavor**

**Use ONLY enclosed syringe**

**2 FL OZ (60 mL)**



## INFANTS PAIN AND FEVER

acetaminophen suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-168
<b>Route of Administration</b>	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)	
CHERRY (UNII: BUC5I9595W)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
NONCRYSTALLIZING SORBITOL SOLUTION (UNII: 9E0S3UM200)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-168-11	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(58602-168) , MANUFACTURE(58602-168)