

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

**Aurohealth LLC**

*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.*

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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.
- for more than 10 days for pain unless directed by a doctor.

- for more than 3 days for fever unless directed by a doctor.
- 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**

- symptoms do not improve
- new symptoms occur
- pain or fever persists or gets worse

**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). Prompt 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**

<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Dose (mL)*</b>
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***

- **each 5 mL contains:** sodium 6 mg
- store at 20°-25°C (68°-77°F)
- **do not use if printed bottle body wrap is broken or missing**
- see bottom panel for lot number and expiration date

***Inactive ingredients***

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

**Questions or comments?**

**1-855-274-4122**

**Distributed by:** Aurohealth LLC.  
2572 Brunswick Pike  
Lawrenceville, NJ 08648

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 2 FL OZ (59 mL)**

NDC 58602-502-11

**PrimaryHealth**

**Infants'**

**Pain & Fever**

**SUSPENSION LIQUID**

**Pain Reliever &**

**Fever Reducer**

**ACETAMINOPHEN**

**ORAL SUSPENSION**

**160 mg per 5 mL**

**- Alcohol Free**

**- Aspirin Free**

**- Ibuprofen Free**

**- Gluten Free**

**Dye-Free Cherry Flavor**

**IMPORTANT:** Use enclosed syringe **ONLY**.

**DO NOT USE** other cups or spoons.

**DO NOT USE IF PRINTED BOTTLE BODY**

**WRAP IS BROKEN OR MISSING**

**2 FL OZ (59 mL)**

NDC 58602-502-11  
**PrimaryHealth**

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 SUSPENSION LIQUID

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**2 FL OZ (59 mL)**

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

**Purpose**

**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. ■ for more than 10 days for pain unless directed by a doctor. ■ for more than 3 days for fever unless directed by a doctor. ■ 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** ■ symptoms do not improve ■ new symptoms occur ■ pain or fever persists or gets worse. **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). Prompt 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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**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°-25°C (68°-77°F)

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

**Questions or comments?** © 1 - 855 - 274 - 4122  
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 2572 Brunswick Pike, Lawrenceville, NJ 08648

300100604  
 LOT  
 EXP

Unvarnished Zone  
 (dotted line not for printing)

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 2 FL OZ (59 mL)**

NDC 58602-502-11  
**PrimaryHealth**  
**COMPARE TO** Infants'  
**TYLENOL®** Oral Suspension  
 active ingredient\*\*  
**Infants'**  
**Pain &**  
**Fever**  
 SUSPENSION LIQUID  
**Pain Reliever & Fever Reducer**  
**ACETAMINOPHEN**  
**ORAL SUSPENSION**  
**160 mg per 5 mL**  
 - Alcohol Free  
 - Aspirin Free  
 - Ibuprofen Free  
 - Gluten Free  
**Dye-Free**  
**Cherry Flavor**  
 Use ONLY enclosed syringe  
**2 FL OZ (59 mL)**



## INFANTS PAIN AND FEVER

acetaminophen suspension

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-502
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BUTYL PARABEN (UNII: 3QP11U3FV8)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
CHERRY (UNII: BUC5I9595W)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
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:58602-502-11	1 in 1 CARTON	09/24/2018	
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	09/24/2018	

**Labeler** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
Aurohealth LLC		078728447	MANUFACTURE(58602-502)