

CHILDRENS 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.

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: Taking more than the recommended dose (overdose) may cause liver damage. 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 below. If possible, use weight to dose; otherwise, use age.
- remove the child protective cap and squeeze your child's dose into the dosing cup
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

Weight (lb)	Age (yr)	Dose (mL)*
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 mL
36-47	4-5 years	7.5 mL
48-59	6-8 years	10 mL
60-71	9-10 years	12.5 mL
72-95	11 years	15 mL

* or as directed by a doctor

Attention: use only enclosed dosing cup 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 seal over cap is torn 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 4 FL OZ (118 mL)

NDC 58602-503-24

PrimaryHealth

Ages 2-11 years

Children's

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 dosage cup

DO NOT USE IF PRINTED SEAL OVER

CAP IS TORN OR MISSING

4 FL OZ (118 mL)

NDC 58602-503-24


Ages 2-11 years
 Children's
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 dosage cup

DO NOT USE IF PRINTED SEAL OVER CAP IS TORN OR MISSING

4 FL OZ (118 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:** Taking more than the recommended dose (overdose) may cause liver damage. 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 below.

If possible, use weight to dose; otherwise, use age. ■ remove the child protective cap and squeeze your child's dose into the dosing cup ■ repeat dose every 4 hours while symptoms last ■ do not give more than 5 times in 24 hours

Weight (lb)	Age (yr)	Dose (mL)*
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 mL
36-47	4-5 years	7.5 mL
48-59	6-8 years	10 mL
60-71	9-10 years	12.5 mL
72-95	11 years	15 mL

* or as directed by a doctor

Attention: use only enclosed dosing cup 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 seal over cap is torn or missing

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

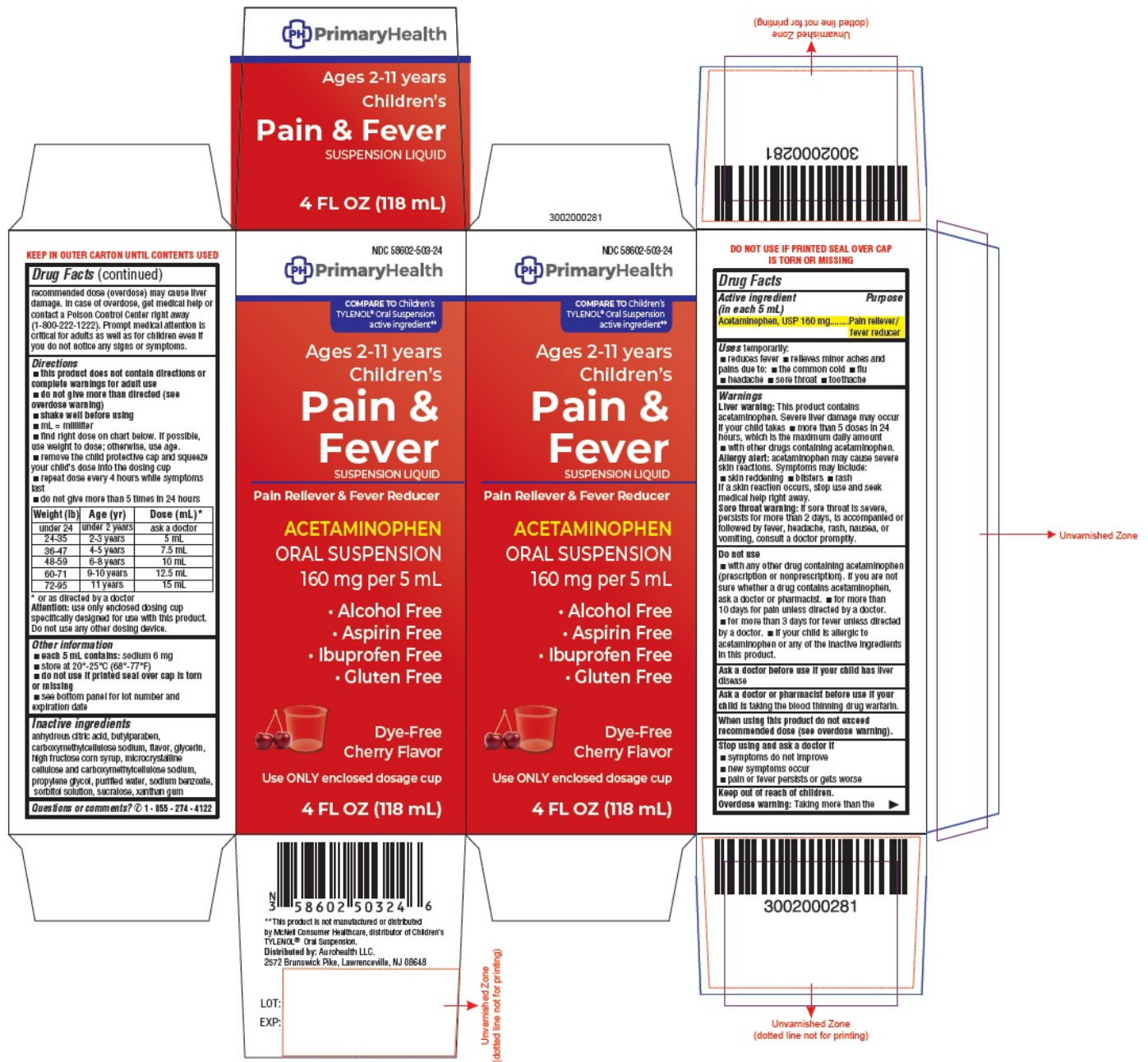
Distributed by: Aurohealth LLC.
 2572 Brunswick Pike, Lawrenceville, NJ 08648

3001000605
 LOT:
 EXP:

Unvarnished Zone
 (dotted line not for printing)

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 4 FL OZ (118 mL)

NDC 58602-503-24
PrimaryHealth
Compare To Children's
 TYLENOL® Oral Suspension
 active ingredient**
Ages 2-11 years
Children's
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 dosage cup
4 FL OZ (118 mL)



CHILDRENS PAIN AND FEVER

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-503
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: 3QP1U3FV8)	
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:58602-503-24	1 in 1 CARTON	09/24/2018	
1		118 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(58602-503)