

## **CHILDRENS ACETAMINOPHEN ORAL SUSPENSION- acetaminophen suspension American Health Packaging**

*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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### **Childrens Acetaminophen Oral Suspension Drug Facts**

#### **Active ingredient**

**(in each 5 mL)**

**Acetaminophen**160 mg

#### **Purpose**

Pain reliever/fever reducer

#### **Use temporarily:**

- reduces fever
- 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 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:**

- 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 children even if you do not notice any sign 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
- find right dose on chart below. If possible, use weight to dose; otherwise, use age
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

<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 (1 unit dose cup)
36-47	4-5 years	7.5 mL (1.5 unit dose cups)
48-59	6-8 years	10 mL (2 unit dose cups)
60-71	9-10 years	12.5 mL (2.5 unit dose cups)

72-95	11 years	15 mL (3 unit dose cups)
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\* or as directed by a doctor

### ***Other information***

- **each 5 mL contains:**sodium: 2 mg
- Store at 20° to 25°C (68° to 77°F)  
grape flavored suspension supplied in the following oral dosage form:  
5 mL unit dose cups: 100 cups (10 x 10) NDC 60687-762-17

### ***Inactive Ingredients:***

acesulfame K, butylparaben, citric acid, flavoring, glycerin, high fructose corn syrup, polysorbate 80, propylene glycol, purified water, sodium benzoate, sorbitol solution, veegum and xanthan gum.

### ***Questions or Comments?***

Call 1-800-845-8210.

**DO NOT USE IF SEAL IS BROKEN.**

Distributed by:

**American Health Packaging**

Columbus, OH 43217

T0966C050423

R04/23

**Principal Display Panel - Tray - 160 mg/5 mL**

Case NDC 60687-762-17/Cup NDC 60687-762-40

**Children's Acetaminophen  
Oral Suspension  
160 mg per 5 mL**

***DYE FREE/GRAPE FLAVOR***

*Ibuprofen Free/Alcohol Free/Aspirin Free*

Pain Reliever-Fever Reducer

**SHAKE WELL BEFORE USING**

**USUAL DOSAGE:** See attached Drug Facts

Store at 20° to 25°C (68° to 77°F)

**For Institutional Use Only.**

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**Principal Display Panel - Cup - 160 mg/5 mL**



NDC 60687- **762**-40

**CHILDREN'S  
ACETAMINOPHEN**  
ORAL SUSPENSION

**Pain Reliever-Fever Reducer**

**160 mg per 5 mL**

DYE FREE/GRAPE FLAVOR

Ibuprofen Free/Alcohol Free/Aspirin Free

**Delivers 5 mL**

SHAKE WELL BEFORE USING

See package Drug Facts insert for full  
prescribing information and storage.

For Institutional Use Only.

American Health Packaging  
Columbus, OH 43217

F0966C50423

## CHILDRENS ACETAMINOPHEN ORAL SUSPENSION

acetaminophen suspension

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60687-762
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		
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)				
BUTYLPARABEN (UNII: 3QPI1U3FV8)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
GLYCERIN (UNII: PDC6A3C0OX)				
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SORBITOL SOLUTION (UNII: 8KW3E207O2)				
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)				
XANTHAN GUM (UNII: TTV12P4NEE)				
Product Characteristics				
Color	white (to off-white appearance)	Score		
Shape		Size		
Flavor	GRAPE (grape flavor)	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60687-762-17	10 in 1 CASE	08/01/2023	
1	NDC:60687-762-46	10 in 1 TRAY		
1	NDC:60687-762-40	5 mL in 1 CUP, UNIT-DOSE; 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		08/01/2023	

**Labeler** - American Health Packaging (929561009)