

**ACETAMINOPHEN ORAL SOLUTION- acetaminophen 160mg/5ml solution**  
**Aldama Pharmaceuticals, Inc**

-----  
**Acetaminophen Oral Solution**

**Active ingredient (in each 5 mL-teaspoonful)**

Acetaminophen 160mg

**Purpose**

Pain reliever/fever reducer

**Uses**

- Temporarily relieves minor aches and pains due to:
  - headache
  - muscular aches
  - backache
  - minor pain of arthritis
  - the common cold
  - toothache
  - premenstrual and menstrual cramps
  - temporarily reduces fever

**Warnings**

**Liver warning**

This product contains acetaminophen. Severe liver damage may occur if:

- if adults takes more than 6 doses in 24 hours, which is the maximum daily amount
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks everyday while using the product.

**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.

**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.

**Ask a doctor before use if your child**has liver disease

**Ask a doctor before use if you have** taking the blood thinning drug warfarin.

**When using this product do not exceed recommended dose**

**Stop use and ask a doctor if**

- pain gets worse or lasts more than 10 days in adults 5 days
- pain gets worse or lasts more than 5 days in children under 12 years
- 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.**

In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults/children even if you do not notice any signs or symptoms

**If pregnant or breast-feeding**

ask a health professional before use

**Directions**

- find dose in chart below
- if possible, use weight to dose, otherwise use age
- dosage may be repeated every 4 hours, or as directed by a doctor
- do not give more than 5 doses in 24 hours

Weight (lbs)	Weight (lbs)	Weight (lbs)	Weight (lbs)	Weight (lbs)	Weight (lbs)	Weight (lbs)	Weight (lbs)
Age (years)	Under 2	2 to 3	4 to 5	6 to 8	9 to 10	11	12 to adult
Dosage teaspoonful (tsp)	consult Physician	1 tsp (5 ml)	1 1/2 tsp (7.5ml)	2 tsp (10 ml)	2 1/2 tsp (12.5ml)	3 tsp (15 ml)	4 tsp (20 ml)

**Other information**

- for institutional or pharmacy use only
- store at room temperature between 15-30°C (59-86°F)
- do not freezing
- protect from light
- TAMPER EVIDENT do not use if foil seal over bottle opening is torn, broken or missing

**Inactive Ingredient**

artificial and natural cherry flavor, citric acid, methylparaben, polyethylene glycol, propylene glycol, propylparaben, purified water, sodium citrate, sucralose

**Question or Comments?**

call 305-592-9216 or [info@aldamapharm.com](mailto:info@aldamapharm.com)



## ACETAMINOPHEN ORAL SOLUTION

acetaminophen 160mg/5ml solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73564-816
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
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
POLYETHYLENE GLYCOL 350 (UNII: ZBR3T82M2V)	

<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)				
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)				
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)				
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)				
<b>Product Characteristics</b>				
<b>Color</b>		<b>Score</b>		
<b>Shape</b>		<b>Size</b>		
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:73564-816-16	1 in 1 BOX	01/01/2026	
1		473 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC Monograph Drug	M013	01/01/2026		

**Labeler** - Aldama Pharmaceuticals, Inc (119484030)

Establishment			
Name	Address	ID/FEI	Business Operations
Aldama Pharmaceuticals, Inc		119484030	manufacture(73564-816)