

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



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)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

METHYLPARABEN (UNII: A2I8C7HI9T)

PROPYLPARABEN (UNII: Z8IX2SC1OH)

SODIUM CITRATE (UNII: 1Q73Q2JULR)

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73564-816-16	1 in 1 BOX	01/01/2026	
1		473 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	01/01/2026	

Labeler - Aldama Pharmaceuticals, Inc (119484030)

Establishment

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

Revised: 1/2026

Aldama Pharmaceuticals, Inc