

**CHILDRENS NON ASPIRIN - acetaminophen liquid**  
**Kareway Product, Inc.**

*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 = 1 teaspoon)**

Acetaminophen 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**

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

**Do not use**

- with any other product containing acetaminophen

**Stop use and ask a doctor if**

- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts for more than 5 days
- fever gets worse or lasts for more than 3 days

**Keep out of reach of children.**

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**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 (1-800-222-1222) right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

**Directions**

**do not give more than directed (see overdose warning)**

- shake well before using
- find right dose on chart below. If possible use weight to dose; otherwise, use age.
- if needed, repeat dose every 4 hours
- do not give more than 5 times in 24 hours

Weight (lb)	Age (yr)	Dose (tsp or mL)
under 24	under 2	ask a doctor
24-35	2-3	1 tsp or 5 mL
36-47	4-5	1 1/2 tsp or 7.5 mL
48-59	6-8	2 tsp or 10 mL
60-71	9-10	2 1/2 tsp or 12.5 mL
72-95	11	3 tsp or 15 mL

**Attention:** use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.

**Other information**

- each teaspoon contains: **sodium 1 mg**
- **do not use if bottle wrap, or foil inner seal imprinted "SEALED for YOUR PROTECTION" is broken or missing**
- store between 20-25°C (68-77°F)
- see bottom panel for lot number and expiration date

**Inactive ingredients**

propylparaben, carboxymethylcellulose sodium, citric acid, corn syrup, FD and C red #40, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, sucrose, xanthan gum

**Package label**

Children's Non-Aspirin



## CHILDRENS NON ASPIRIN

acetaminophen liquid

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:67510-0508

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
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CORN SYRUP (UNII: 9G5L16BK6N)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0508-4	120 mL in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	09/02/2011	

**Labeler** - Kareway Product, Inc. (121840057)

Revised: 9/2011

Kareway Product, Inc.