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.

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
 - o 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.

Enter section text here

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



Drug Facts

Active ingredient Purpose (in each 5mL = 1 teaspoon) Pain reliever, Acetaminophen 160 mg.....fever reduced

Uses temporarily:

Warnings
Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, neusea, or vomitting, 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

Keep out of reach of children.

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Drug Facts (continued)

- Directions do not give more than directed (see overdose warning)

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 do not give more than 5 times in 24 hours
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 expiration date

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

This product is not manufactured by McNeil, owner of the registered trademark Children's Tylenol &.

Exclusively distributed by: Kareway Product Inc. Gardena, CA 90248 Made in Korea

For ages 2 to 11 Children's

Pain Reliever/Fever Reducer



contains Acetaminophen

Oral Suspension 80 mg per 1/2 teaspoon (160 mg per 5 mL)

> Cherry Flavor Alcohol Free Aspirin Free Ibuprofen Free

4FL OZ (120mL)



For ages 2 to 11 Children's

Pain Reliever/Fever Reducer



Oral Suspension 80 mg per 1/2 teaspoon (160 mg per 5 mL)

Cherry Flavor

Alcohol Free Aspirin Free Ibuprofen Free

4FL OZ (120mL)



EXP: LOT:

CHILDRENS NON ASPIRIN

acetaminophen liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:67510-0508

ORAL

| Active | Ingredient/Active | Moiety |
|--------|-------------------|--------|
|--------|-------------------|--------|

| ricave ingredient/retive wrotety | | | |
|----------------------------------|---|-------------------|----------------|
| I | Ingredient Name | Basis of Strength | Strength |
| l | ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D) | ACETAMINOPHEN | 160 mg in 5 mL |

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | | |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311) | | |
| CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP) | | |
| CORN SYRUP (UNII: 9G5L16BK6N) | | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | | |
| GLYCERIN (UNII: PDC6 A3C0 OX) | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | |
| WATER (UNII: 059QF0KO0R) | | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | | |
| SORBITOL (UNII: 506T60A25R) | | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | | |
| SUCROSE (UNII: C151H8M554) | | |
| XANTHAN GUM (UNII: TTV12P4NEE) | | |

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

| Marketing Inform | Marketing Information | | | |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part343 | 09/02/2011 | | |
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Labeler - Kareway Product, Inc. (121840057)

Revised: 9/2011 Kareway Product, Inc.