COUNTERACT CHILDRENS PAIN RELIEVER- acetaminophen suspension Melaleuca, 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.

CounterAct Children's Pain Reliever Content of label

Active ingredient (in each 5 mL teaspoon)

Acetaminophen 160 mg

Purpose

Pain reliever/fever reducer

Use temporarily:

- reduces fever
- relieves minor aches and pains due to:
- the common cold
 - o 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

Sore throat warning: If sore throat is severe, or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

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 or pharmacist before use if your child is taking the blood thinning drug warfarin

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. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical even if you do not notice any signs or symptoms.

Directions

- do not give more than directed (see Liver warning)
- shake well before use
- find right dose on chart. If possible, use weight to dose; otherwise use age.
- use only enclosed dosing cup designed for use with this product. Do not use any other dosing

device.

- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give for more than 5 days unless directed by a doctor
- this product does not contain directions or complete warnings for adult use

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

- store at 20°-25°C (68°-77°F)
- each teaspoon contains: sodium 3 mg
- do not use if printed neckband is broken or missing

Inactive ingredients anhydrous citric acid, butylparaben, carboxymethylcellulose sodium, carrageenan, FD and C red no. 40, flavor, glycerin, high fructose corn syrup, hydroxyethyl cellusose, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol solution

Questions or comments? 1-800-282-3000

175-002 ELA14A-1 ELA 14A

Active ingredient (in each 5 mL = 1 teaspoon) Acetaminophen 160 mg.

Purpose Pain reliever/fever reduce

Uses temporarily:

- relieves minor aches and pains due to:
 flu headache sore throat toothache ■ flu ■ 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

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 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 or pharmacist before use if your child is taking

the blood thinning drug warfarin

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. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical even if you do not notice any signs or symptoms.

Directions ■ do not give more than directed (see Liver warning)
■ shake well before using ■ find right dose on chart. If possible, use weight to dose; otherwise, use age. ■ use only enclosed dosing cup designed for use with this product. Do not use any other dosing device.

CounterAct^e

SEE NEW WARNINGS INFORMATION

PHARMACY

EUCA

MELALE



Acetaminophen **Oral Suspension Liquid**

DO NOT USE

IF PRINTED

NECKBAND

IS BROKEN

OR MISSING

Fever Reducer Pain Reliever

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

4 FL OZ (118 mL)

■ if needed, repeat dose every 4 hours while symptoms last ■ do not give more than 5 times in 24 hours ■ do not give for more than 5 days unless directed by a doctor ■ this product does not contain directions or complete

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*Other information**

■ each teaspoon contains: sodium 3 mg

■ store at 20°-25°C (68°-77°F)

■ store at 20 − 25 € (86 − 17 + 17)

Inactive ingredients anhydrous citric acid, butylparaben, carboxymethylcellulose sodium, carrageenan, FD&C red no. 40, flavor, glycerin, high fructose corn syrup, hydroxyethyl cellulose, microcrystalline cellulose, propylene glycol, purified water, sodium benzadte expitiol solution. benzoate, sorbitol solution

(Questions or comments? 1-800-282-3000

Dist. by: Melaleuca, Inc. Idaho Falls, ID 83402-6003 To order: 1-800-282-3000 www.melaleuca.com #2255 08/09U

100% Satisfaction Guarantee



: 17526 MB F5



acetaminophen suspension

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-098	
Route of Administration	ORAL			

l	Active Ingredient/Active Moiety			
l	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
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)	
CARRAGEENAN (UNII: 5C69 YCD2YJ)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTO SE CORN SYRUP (UNII: XY6 UN3QB6S)	
HYDROXYETHYL CELLULOSE (4000 MPA.S FOR 1% AQUEOUS SOLUTION) (UNII: ZYD53NBL45)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	red (Red)	Score	
Shape		Size	
Flavor	CHERRY (cherry)	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:54473-098-04	1 in 1 BOX		
1	5 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	0 1/12/20 10	

Labeler - Melaleuca, Inc. (139760102)

Revised: 3/2011 Melaleuca, Inc.