

CAREONE CHILDRENS PAIN AND FEVER- acetaminophen suspension
American Sales Company

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.

American Sales Company Children's Pain & Fever Drug Facts

Active ingredient (in each 5 mL = 1 teaspoonful)

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

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.
- if your child has ever had an allergic reaction to this product or any of its ingredients

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

When using this product

do not exceed recommended dose (see overdose warning)

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.

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

Directions

- this product does not contain directions or complete warnings for adult use
- do not give more than directed (see overdose warning)
- shake well before using
- mL = milliliter; tsp = teaspoonful
- find right dose on chart. If possible, use weight to dose; otherwise, use age.
- remove the child protective cap and squeeze your child's dose into the dosing cup
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

Weight (lb)	Age (yr)	Dose (mL or tsp)*
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 mL (1 tsp)
36-47	4-5 years	7.5 mL (1 ½ tsp)
48-59	6-8 years	10 mL (2 tsp)
60-71	9-10 years	12.5 mL (2 ½ tsp)
72-95	11 years	15 mL (3 tsp)

*or as directed by a doctor

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

Other information

- each 5 mL (1 tsp) contains: sodium 3 mg
- store at 20-25°C (68-77°F)
- do not use if printed neckband is broken or missing

Inactive ingredients

anhydrous citric acid, butylparaben, calcium sulfate, carrageenan, D&C red #33, FD&C blue #1, flavor, glycerin, high fructose corn syrup, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, tribasic sodium phosphate

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to the Active Ingredient in Children's Tylenol® Oral Suspension

CHILDREN'S PAIN & FEVER

Pain Reliever/Fever Reducer

Acetaminophen

Oral Suspension 160 mg per 5 mL

GRAPE FLAVOR

AGES 2-11

Alcohol Free

Aspirin Free

Ibuprofen Free

4 FL OZ (118 mL)

CAREONE®

**CHILDREN'S
PAIN & FEVER**

Pain Reliever/Fever Reducer

Acetaminophen

Oral Suspension 160 mg per 5 mL

GRAPE FLAVOR
AGES 2-11

*Compare to the Active
Ingredient in
Children's Tylenol®
Oral Suspension†*

NDC 41520-061-26

CAREONE®

**CHILDREN'S
PAIN & FEVER**

Pain Reliever/Fever Reducer

Acetaminophen

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GRAPE FLAVOR
AGES 2-11

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AGES 2-11

*Alcohol Free
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Ibuprofen Free*



4 FL OZ
(118 mL)



LOT NO.

EXP. *Code Area*

: 13026 D4 C5





Drug Facts

Active ingredient Purpose (in each 5 mL = 1 teaspoonful)

Acetaminophen 160 mg...Pain reliever/fever reducer

Uses temporarily:

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 - the common cold
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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

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Stop use and ask a doctor if

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Drug Facts (continued)

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Questions or comments?

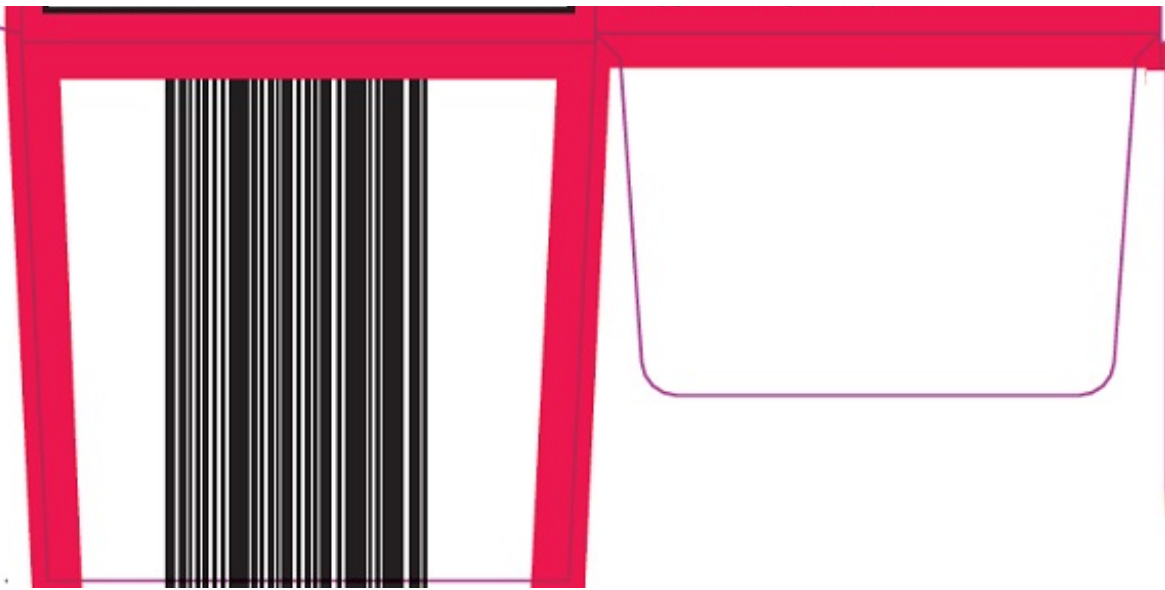
1-800-719-9260

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Tylenol® Oral Suspension.

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GLUTEN FREE

Quality guaranteed or your money back.



CAREONE CHILDRENS PAIN AND FEVER

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:41520-061
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (ACETAMINOPHEN)	ACETAMINOPHEN	160 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID	
BUTYLPARABEN	
CARRAGEENAN	
D&C RED NO. 33	
FD&C BLUE NO. 1	
GLYCERIN	
HIGH FRUCTOSE CORN SYRUP	
CELLULOSE, MICROCRYSTALLINE	
CARBOXYMETHYLCELLULOSE SODIUM	
PROPYLENE GLYCOL	
WATER	
SODIUM BENZOATE	
SORBITOL	
SODIUM PHOSPHATE, TRIBASIC	
CALCIUM SULFATE	

Product Characteristics

Color	PURPLE (viscous)	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-061-26	1 in 1 CARTON		
1		118 mL in 1 BOTTLE		
2	NDC:41520-061-28	1 in 1 CARTON		
2		147 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/13/2004	

Labeler - American Sales Company (809183973)