

**CARE ONE PAIN RELIEF CHILDRENS- 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.*

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**American Sales Company Children's Pain Relief 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**

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

## 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

- this product does not contain directions or complete warnings for adult use
- 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.
- 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

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

- each teaspoon 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, flavor, glycerin, high fructose corn syrup, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, red #33, red #40, 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 RELIEF

Fever Reducer/Pain Reliever

Acetaminophen Oral Suspension

BUBBLE GUM FLAVOR

AGES 2-11

Alcohol Free

Aspirin Free

Ibuprofen Free

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

4 FL OZ (118 ml)

CAREONE®

**CHILDREN'S  
PAIN RELIEF**

*Fever Reducer/Pain Reliever*  
Acetaminophen Oral Suspension

**BUBBLE GUM FLAVOR**  
AGES 2-11

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

CAREONE®

**CHILDREN'S  
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*Fever Reducer/Pain Reliever*  
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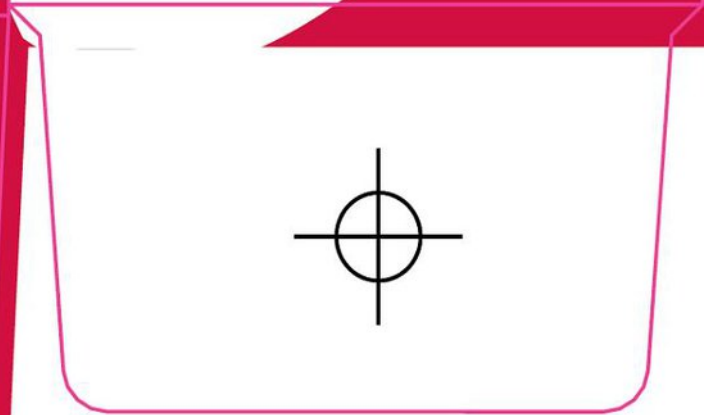
**4 FL OZ**  
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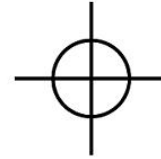
LOT NO.

EXP. *Code Area*

: 10526 D4 C4



Children's Pain Relief Carton Image 1



### Drug Facts

#### Active ingredient Purpose (in each 5 mL = 1 teaspoon)

Acetaminophen 160 mg...Pain reliever/fever reducer

#### Uses temporarily:

- reduces fever
- relieves minor aches and pains due to:
  - the common cold
  - flu
  - headache
  - sore throat
  - toothache

#### Warnings

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#### Do not use

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- 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**

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### Drug Facts (continued)

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#### Questions or comments?

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\*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Tylenol® Oral Suspension.  
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**DISTRIBUTED BY: AMERICAN SALES COMPANY**  
 4201 WALDEN AVENUE, LANCASTER, NY 14086  
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 Quality guaranteed or your money back.



Children's Pain Relief Carton Image 2

**CARE ONE PAIN RELIEF CHILDRENS**

acetaminophen suspension

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41520-105
<b>Route of Administration</b>	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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BUTYLPARABEN (UNII: 3QP1U3FV8)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
CALCIUM SULFATE (UNII: WAT0DDB505)	
SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X)	

### Product Characteristics

Color	RED (opaque)	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-105-26	1 in 1 CARTON		
1		118 mL in 1 BOTTLE		
2	NDC:41520-105-28	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)