

**CAREONE INFANTS ACETAMINOPHEN- acetaminophen suspension**  
**American Sales Company**

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**American Sales Company Infants' Acetaminophen 160mg PER 5mL Drug Facts**

**Active ingredient (in each 5 mL)**

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

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

**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:** 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
- find right dose on chart. If possible, use weight to dose; otherwise, use age.
- push air out of syringe. Insert syringe tip into bottle opening.
- flip bottle upside down. Pull yellow part of syringe to the first dose line and then push product back into bottle.
- pull yellow part of syringe until it reaches and stays at the correct dose
- dispense liquid slowly into child’s mouth, toward inner cheek
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- replace cap tightly to maintain child resistance

**Dosing Chart**

<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Dose (mL)*</b>
under 24	under 2 years	ask a doctor

24-35	2-3 years	5 mL
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\* or as directed by a doctor

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

### **Other information**

- store at 20-25°C (68-77°F)
- **do not use if printed neckband is broken or missing**

### **Inactive ingredients**

anhydrous citric acid, calcium sulfate, carrageenan, FD&C red #40, 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**

### **Package/Label Principal Display Panel**

CAREone®

Compare to the active ingredient in Infants' Tylenol® Oral Suspension

For Ages 2 to 3 Years

Infants'

ACETAMINOPHEN

160mg PER 5mL

Pain Reliever/Fever Reducer

Suspension Liquid

Alcohol Free

Aspirin Free

Ibuprofen Free

Gluten Free

Use only with enclosed syringe.

See side panel for more information.

Cherry Flavor

OUR PHARMACISTS RECOMMEND

2 FL OZ (59mL)

**Drug Facts**

**Active ingredient (in each 5 mL)**     **Purpose**  
**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**  
**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  
**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:     ■ skin reddening     ■ blisters     ■ rash  
 If a skin reaction occurs, stop use and seek medical help right away.  
**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**     ■ new symptoms occur  
 ■ pain gets worse or lasts more than 5 days  
 ■ fever gets worse or lasts more than 3 days  
 ■ redness or swelling is present. These could be signs of a serious condition.  
**Keep out of reach of children.**  
**Overdose warning:** 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  
 ■ find right dose on chart. If possible, use weight to dose; otherwise, use age.  
 ■ push air out of syringe. Insert syringe tip into bottle opening.  
 ■ flip bottle upside down. Pull yellow part of syringe to the first dose line and then push product back into bottle.

**Drug Facts (continued)**

■ pull yellow part of syringe until it reaches and stays at the correct dose  
 ■ dispense liquid slowly into child's mouth, toward inner cheek  
 ■ repeat dose every 4 hours while symptoms last  
 ■ do not give more than 5 times in 24 hours  
 ■ replace cap tightly to maintain child resistance

**Dosing Chart**

Weight (lb)	Age (yr)	Dose (mL)*
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 mL

\* or as directed by a doctor  
**Attention:** use only enclosed syringe specifically designed for use with this product. Do not use any other dosing device.

**Other information**  
 ■ store at 20-25°C (68-77°F)  
 ■ **do not use if printed neckband is broken or missing**

**Inactive ingredients**  
 anhydrous citric acid, calcium sulfate, carrageenan, FD&C red #40, 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

\*\*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Infants' Tylenol® Oral Suspension.  
 DISTRIBUTED BY:  
 ADUSA DISTRIBUTION, LLC  
 SALISBURY, NC 28147 • 1-833-992-3872  
 Quality guaranteed or your money back.

NDC 41520-363-16

**CAREone®**

Compare to the active ingredient in Infants' Tylenol® Oral Suspension\*\*

**For Ages 2 to 3 Years**

**Infants'**

**ACETAMINOPHEN**

**160mg PER 5mL**

**Pain Reliever/Fever Reducer**

**Suspension Liquid**

Alcohol Free  
 Aspirin Free  
 Ibuprofen Free  
 Gluten Free



Use only with enclosed syringe. See side panel for more information.

**Cherry Flavor**

**2 FL OZ (59mL)**



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**IMPORTANT:**  
 Please see dosing chart or ask a doctor for your child's correct dose.

**STEP 1.** See *Directions* for the correct dose for your child.

**STEP 2.** Shake well before using.

**STEP 3.** Push air out of syringe. Insert syringe tip into bottle opening.



**STEP 4.** Flip bottle upside down. Pull yellow part of syringe to the first dose line and then push product back into bottle.

**STEP 5.** Pull yellow part of syringe until it reaches and stays at the correct dose.



**STEP 6.** Dispense liquid slowly into child's mouth.

## CAREONE INFANTS ACETAMINOPHEN

acetaminophen suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41520-363
<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)	
CALCIUM SULFATE, UNSPECIFIED FORM (UNII: WAT0DDB505)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X)	

**Product Characteristics**

Color	RED	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-363-10	1 in 1 CARTON	09/22/2017	05/31/2021
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:41520-363-16	1 in 1 CARTON	10/12/2017	
2		59 mL in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	12/14/2016	

