

# **INFANTS FEVER REDUCER AND PAIN RELIEVER- acetaminophen suspension**

## **Rite Aid Corporation**

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### **Rite Aid Corporation Infants' Fever Reducer & Pain Reliever 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

<b>Dosing Chart</b>		
<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, flavor, glycerin, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, tribasic sodium phosphate

### **Questions or comments?**

**1-800-719-9260**

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

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

FREE FROM

DYE FREE

PARABEN FREE

FOR AGES 2-3 YEARS

INFANTS' FEVER REDUCER & PAIN RELIEVER

ACETAMINOPHEN 160 mg/5 mL

oral suspension

aspirin free

ibuprofen free

CHERRY FLAVOR

2 FL OZ (60 mL)

USE ONLY ENCLOSED SYRINGE

SEE SIDE PANEL FOR MORE INFORMATION



**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, flavor, glycerin, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, 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.

**OUR PROMISE:**

Dye Free
 Paraben Free
 Alcohol Free  
 Gluten Free
 Sugar Free

FOR AGES 2-3 YEARS

**INFANTS' FEVER REDUCER & PAIN RELIEVER**

NDC 11822-0590-1

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

**FREE FROM** DYE FREE PARABEN FREE

FOR AGES 2-3 YEARS

**INFANTS' FEVER REDUCER & PAIN RELIEVER**

**ACETAMINOPHEN 160 mg/5 mL oral suspension aspirin free ibuprofen free**



**CHERRY FLAVOR**

USE ONLY ENCLOSED SYRINGE SEE SIDE PANEL FOR MORE INFORMATION

2 FL OZ (60 mL)



**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.

DISTRIBUTED BY: RITE AID 200 NELUBERRY COMMONS ETTERS, PA 17319 www.riteaid.com

**SATISFACTION GUARANTEE**  
 If you're not satisfied, we'll happily refund your money.



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**INFANTS FEVER REDUCER AND PAIN RELIEVER**

acetaminophen suspension

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11822-0590
<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
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>CALCIUM SULFATE, UNSPECIFIED FORM</b> (UNII: WAT0DDB505)	
<b>CARRAGEENAN</b> (UNII: 5C69YCD2YJ)	
<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
<b>HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%)</b> (UNII: R33S7TK2EP)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>SODIUM PHOSPHATE, TRIBASIC</b> (UNII: A752Q30A6X)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0590-1	1 in 1 CARTON	09/08/1993	
1		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	09/08/1993	

**Labeler** - Rite Aid Corporation (014578892)