

# **PAIN AND FEVER- acetaminophen suspension**

## **H E B**

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### **HEB Infants' Pain & Fever 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**

- 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.
- 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**

Compare to Infants' Tylenol® Oral Suspension active ingredient

H-E-B®

Infants' Pain & Fever

Acetaminophen

160 mg per 5 mL

Oral Suspension

Pain Reliever/Fever Reducer

For Ages 2 to 3 Years

Use only with enclosed syringe.

See side panel for more information.

- Alcohol Free
- Aspirin Free
- Ibuprofen Free
- Paraben Free

Cherry Flavor

2 FL OZ (59 mL)



**PAIN AND FEVER**  
 acetaminophen suspension

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37808-161
<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: PDC6A3C00X)	
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:37808-161-16	1 in 1 CARTON	12/15/2011	
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	12/15/2011	

**Labeler** - H E B (007924756)