

## **TOPCARE INFANTS PAIN AND FEVER- acetaminophen suspension**

### **Topco Associates LLC**

*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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### **Topco Associates LLC. 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**

- 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

\* 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 bottle wrap is broken or missing**

### Inactive ingredients

anhydrous citric acid, calcium sulfate, carrageenan, flavor, glycerin, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, propylparaben, purified water, sodium benzoate, sorbitol solution, sucralose, tribasic sodium phosphate

### Questions or comments?

**1-888-423-0139**

### Package/Label Principal Display Panel

TopCare® health

COMPARE TO INFANTS' TYLENOL® ORAL SUSPENSION ACTIVE INGREDIENT

infants' Pain & Fever

ORAL SUSPENSION

ACETAMINOPHEN, 160 mg per 5 mL

PAIN RELIEVER • FEVER REDUCER

DYE-FREE

• Aspirin Free • Ibuprofen Free

• Alcohol Free • Non-Staining

• No High Fructose Corn Syrup

Pediatrician Preferred Dosing System

Use only with enclosed syringe.

## For Children



Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-590	
Route of Administration	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)				
GLYCERIN (UNII: PDC6A3C0OX)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SORBITOL (UNII: 506T60A25R)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X)				
Product Characteristics				
Color	WHITE (viscous)	Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-590-16	1 in 1 CARTON	11/03/2011	
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 not final	part343		07/21/1993	

