

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

### **Cardinal Health**

*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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### **Cardinal Health 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

| 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, butylparaben, calcium sulfate, carrageenan, D&C red #33, FD&C blue #1, 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**

Infants' Pain & Fever

Acetaminophen 160 mg per 5 mL

Oral Suspension

Pain Reliever

Fever Reducer

Grape Flavor

COMPARE TO INFANTS' TYLENOL® ORAL SUSPENSION active ingredient

For Children

Alcohol-Free

Aspirin-Free

Ibuprofen-Free

100% Money Back Guarantee

2 FL OZ (59 mL)

USE ONLY WITH ENCLOSED SYRINGE.

SEE SIDE PANEL FOR MORE INFORMATION.

PEDIATRICIAN PREFERRED DOSING SYSTEM.



## LEADER INFANTS PAIN AND FEVER

acetaminophen suspension

### Product Information

|                         |                |                    |                |
|-------------------------|----------------|--------------------|----------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:70000-0472 |
| 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)         |                  |  |                      |                    |
| BUTYL PARABEN (UNII: 3QPIIU3FV8)                 |                  |  |                      |                    |
| CALCIUM SULFATE (UNII: WAT0DDB505)               |                  |  |                      |                    |
| CARRAGEENAN (UNII: 5C69YCD2YJ)                   |                  |  |                      |                    |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L)                |                  |  |                      |                    |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)               |                  |  |                      |                    |
| GLYCERIN (UNII: PDC6A3C0OX)                      |                  |  |                      |                    |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)      |                  |  |                      |                    |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)   |                  |  |                      |                    |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) |                  |  |                      |                    |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)              |                  |  |                      |                    |
| WATER (UNII: 059QF0KO0R)                         |                  |  |                      |                    |
| SODIUM BENZOATE (UNII: OJ245FE5EU)               |                  |  |                      |                    |
| SORBITOL (UNII: 506T60A25R)                      |                  |  |                      |                    |
| SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X)    |                  |  |                      |                    |
|  |                  |  |                      |                    |
| Product Characteristics                          |                  |  |                      |                    |
| Color  |                  | PURPLE   | Score                |                    |
| Shape  |                  |  | Size                 |                    |
| Flavor   |                  | GRAPE  | Imprint Code         |                    |
| Contains   |                  |  |                      |                    |
|  |                  |  |                      |                    |
| Packaging  |                  |  |                      |                    |
| #  | Item Code        | Package Description                                  | Marketing Start Date | Marketing End Date |
| 1  | NDC:70000-0472-1 | 1 in 1 CARTON  | 03/12/2019           |                    |
| 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  | 03/12/2019           |                    |

**Labeler** - Cardinal Health (097537435)