

## **INFANTS PAIN RELIEF- acetaminophen suspension**

### **P & L Development, 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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### **Drug Facts**

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

**Acetaminophen 160 mg**

#### **Purpose**

**Pain reliever/fever reducer**

#### **Uses**

- temporarily reduces fever
- temporarily 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 non prescription). If

you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

- if your child is allergic to acetaminophen or any of the inactive ingredients in this product.

**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
- redness or swelling is present
- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days

These could be signs of a serious condition.

**Keep out of reach of children.**

**Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. 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 take more than directed (see overdose warning)**
- **shake well before using**
- mL=milliliter
- only use the enclosed syringe.

**Do not use any other syringe, dropper, spoon or dosing device when giving this medicine to your child.**

- remove cap and insert syringe into hole at top of bottle until it snap into place and turn upside down.
- pull back syringe until filled to the prescribed level. if you pass the prescribed level, invert assembly to right side up on a flat surface and simply push syringe back until you have reached the desired level. Slowly dispense the liquid into your child's mouth (towards inner cheek).
- if needed, repeat dose every 4 hours while symptoms last.
- do not use give more than 5 times in 24 hours
- do not give more than 5 days unless directed by a doctor

- replace cap tightly to maintain child resistance
- find the right dose on chart below. If possible, use weight to dose; otherwise, use age.

| <b>Weight (lb)</b> | <b>Age (year)</b> | <b>Dose (mL)*</b> |
|--------------------|-------------------|-------------------|
| under 24           | under 2           | ask a doctor      |
| 24-35              | 2-3               | 5 mL              |

\*or as directed by a doctor

### **Other information**

- store between 20-25°C (68-77°F)
- do not refrigerate.
- see bottom panel for lot number and expiration date

### **Inactive ingredients**

anhydrous citric acid, butylparaben, carboxymethylcellulose sodium, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

### **Questions or comments?**

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

### **Principal Display Panel**

infants' dye-free pain reliever

acetaminophen 160 mg per 5 mL

oral suspension

pain reliever & fever reducer

- alcohol free
- aspirin free
- ibuprofen free

for ages 2-3 years

enhanced dosing system reduces the chance of accidental ingestion and overdose

FL OZ (mL)

Use Only Enclosed Syringe

Grape flavor

\*\*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Infants' Tylenol® Oral Suspension.

**TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR PRINTED SAFETY SEAL AROUND BOTTLE IS BROKEN OR MISSING.**

Distributed by: PL Developments

200 Hicks Street, Westbury, NY 11590

**Package Label**

| <p><b>Drug Facts</b></p> <p><b>Active ingredient (in each 5 mL)</b> <span style="float:right"><b>Purpose</b></span><br/>         Acetaminophen 160 mg.....Pain reliever/fever reducer</p> <p><b>Uses</b> ■ temporarily reduces fever<br/>         ■ temporarily relieves minor aches and pains due to<br/>         ■ the common cold ■ flu ■ headache ■ sore throat ■ toothache</p> <p><b>Warnings</b><br/> <b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if your child takes:<br/>         ■ more than 5 doses in 24 hours, which is the maximum daily amount<br/>         ■ with other drugs containing acetaminophen<br/> <b>Allergy alert:</b> Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash<br/>         If a skin reaction occurs, stop use and seek medical help right away.<br/> <b>Sore throat warning:</b> 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.</p> <p><b>Do not use</b><br/>         ■ with any other drug containing acetaminophen (prescription or nonprescription).<br/>         If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.<br/>         ■ if your child is allergic to acetaminophen or any of the inactive ingredients in this product</p> <p><b>Ask a doctor before use if your child has liver disease.</b></p> <p><b>Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin.</b></p> <p><b>When using this product, do not exceed recommended dose (see Overdose warning).</b></p> <p><b>Stop use and ask a doctor if</b><br/>         ■ new symptoms occur ■ redness or swelling is present<br/>         ■ pain gets worse or lasts more than 5 days<br/>         ■ fever gets worse or lasts more than 3 days<br/>         These could be signs of a serious condition.</p> <p><b>Keep out of reach of children.</b></p> <p><b>Overdose warning:</b> Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical even if you do not notice any signs or symptoms.</p> <p><b>Directions</b><br/>         ■ this product does not contain directions or complete warnings for adult use<br/>         ■ do not take more than directed (see Overdose warning)<br/>         ■ shake well before using</p> | <p><b>Drug Facts (continued)</b></p> <p>■ mL = milliliter<br/>         ■ only use the enclosed syringe. Do not use any other syringe, dropper, spoon or dosing device when giving this medicine to your child.</p> <p>■ remove cap, insert syringe into hole at top of bottle until it snaps into place and turn upside down<br/>         ■ pull back syringe until filled to the prescribed level. If you pass the prescribed level, invert assembly to right side up on flat surface and simply push syringe back until you have reached the desired level. Slowly dispense the liquid into your child's mouth (towards inner cheek).<br/>         ■ if needed, repeat dose every 4 hours while symptoms last<br/>         ■ do not give more than 5 times in 24 hours<br/>         ■ do not give more than 5 days unless directed by a doctor<br/>         ■ replace cap tightly to maintain child resistance<br/>         ■ find the right dose on chart below. If possible, use weight to dose; otherwise, use age.</p> <table border="1"> <thead> <tr> <th>Weight (lb)</th> <th>Age (year)</th> <th>Dose (mL)*</th> </tr> </thead> <tbody> <tr> <td>under 24</td> <td>under 2</td> <td>ask a doctor</td> </tr> <tr> <td>24-35</td> <td>2-3</td> <td>5 mL</td> </tr> </tbody> </table> <p>*or as directed by a doctor</p> <p><b>Other information</b><br/>         ■ store between 20-25°C (68-77°F)<br/>         ■ do not refrigerate<br/>         ■ see bottom panel for lot number and expiration date</p> <p><b>Inactive ingredients</b> butylparaben, carboxymethylcellulose sodium, citric acid, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum</p> <p><b>Questions or comments?</b> Call 1-877-753-3835 Monday-Friday 9AM-5PM EST</p> <p><small>**This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Infants' Tylenol® Oral Suspension.</small></p> | Weight (lb)  | Age (year) | Dose (mL)* | under 24 | under 2 | ask a doctor | 24-35 | 2-3 | 5 mL | <div style="text-align: center;">  <p>infants' dye-free<br/>pain reliever</p> <p>acetaminophen<br/>160 mg per 5 mL<br/>oral suspension<br/>pain reliever &amp; fever reducer</p> <ul style="list-style-type: none"> <li>• alcohol free</li> <li>• aspirin free</li> <li>• ibuprofen free</li> </ul> <p>for ages 2-3 years</p> <p>enhanced dosing system<br/>reduces the chance of<br/>accidental ingestion<br/>and overdose.</p> <p>use only enclosed syringe</p> <p>2 fl oz (59 mL) <span style="float:right">grape<br/>flavor</span></p> <p>**Compare to the active ingredient in<br/>Infants' Tylenol® Oral Suspension</p> </div> | <p style="border: 1px solid black; padding: 2px; text-align: center;">TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF PRINTED SAFETY SEAL AROUND THE BOTTLE IS BROKEN OR MISSING.</p> <p>Distributed by: <b>PL Developments</b><br/>         200 Hicks Street, Westbury, NY 11590</p> <p>PLD-A2700 F0004681</p> |
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Lot No:  
Exp. Date:

**WELNESS BASICS Infants Dye-Free Pain Reliever Grape Flavor**

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>INFANTS PAIN RELIEF</b>     |                |                           |                |
| acetaminophen suspension       |                |                           |                |
| <b>Product Information</b>     |                |                           |                |
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:49580-0623 |
| <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)         |          |
| BUTYLPARABEN (UNII: 3QPI1U3FV8)                  |          |
| GLYCERIN (UNII: PDC6A3C0OX)                      |          |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)      |          |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)   |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)              |          |
| WATER (UNII: 059QF0KO0R)                         |          |
| SODIUM BENZOATE (UNII: OJ245FE5EU)               |          |
| SORBITOL (UNII: 506T60A25R)                      |          |
| SUCRALOSE (UNII: 96K6UQ3ZD4)                     |          |
| XANTHAN GUM (UNII: TTV12P4NEE)                   |          |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) |          |

**Product Characteristics**

|          |       |              |  |
|----------|-------|--------------|--|
| Color    |       | Score        |  |
| Shape    |       | Size         |  |
| Flavor   | GRAPE | Imprint Code |  |
| Contains |       |              |  |

**Packaging**

| # | Item Code        | Package Description                                           | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:49580-0623-2 | 1 in 1 BOX                                                    | 01/31/2018           | 02/28/2025         |
| 1 |                  | 59 mL in 1 BOTTLE, PLASTIC; 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                                  | 01/31/2018           | 02/28/2025         |

**Labeler** - P & L Development, LLC (101896231)