

**CHILDRENS PAIN RELIEF ORAL SUSPENSION- acetaminophen suspension**  
**Pharmacy Value Alliance, LLC**

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**Childrens Pain Relief ORAL SUSPENSION Cherry Flavor**

**Drug Facts**

**Active ingredient** (in each 5 mL =1 teaspoonful)

Acetaminophen 160 mg

**Purpose**

Acetaminophen.... 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,

**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 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**

■ 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**

### **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 right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

### **Directions**

■ **this product does not contain directions or complete warnings for adult use.**

■ **shake well before using**

■ mL = milliliter; tsp = teaspoonful

■ find right dose on chart below. If possible, use weight to dose; otherwise, use age.

■ if needed, repeat dose every 4 hours while symptoms last

■ do not give more than 5 times in 24 hours

■ do not give for more than 5 days unless directed by a doctor.

| <b>Weight (lb)</b> | <b>Age (yr)</b> | <b>Dose (mL or tsp)*</b> |
|--------------------|-----------------|--------------------------|
| under 24           | under 2 years   | ask a doctor             |
| 24-35              | 2-3 years       | 5 mL (1 tsp)             |
| 36-47              | 4-5 years       | 7.5 mL (1 1/2 tsp)       |
| 48-59              | 6-8 years       | 10 mL (2 tsp)            |
| 60-71              | 9-10 year       | 12.5 mL (2 1/2 tsp)      |
| 72-95              | 11 year         | 15 mL (3 tsp)            |

\*or as directed by a doctor

**Attention:** use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.

### **Other information**

■ each 5 mL (1 tsp) contains: sodium 3 mg

■ store between 20-25°C (68-77°F)

■ do not refrigerate

■ **Keep carton for full directions for use.**

**Inactive ingredients** anhydrous citric acid, butylparaben, FD&C red #40, flavor, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution,

sucralose, xanthan gum

**Questions?** Call weekdays from 9:30 AM to 4:30 PM EST at **1-877-798-5944**

**Principal Display Panel**

**Premier  
Value®**

**Children's  
Pain Relief**

**PAIN RELIEVER - FEVER REDUCER  
ACETAMINOPHEN**

**ORAL SUSPENSION**

**Cherry Flavor**

**Premier  
Value®**

Compare to the active ingredients in Children's TYLENOL® Oral Suspension\*\*

**Ages 2-11 years**

**Children's  
Pain Relief**

**PAIN RELIEVER - FEVER REDUCER  
ACETAMINOPHEN**

**ORAL SUSPENSION**

**160 mg per 5 mL**

- **Alcohol Free**
- **Aspirin Free**
- **Ibuprofen Free**

**Use ONLY enclosed  
dosage cup**

**Cherry Flavor**  
4 FL OZ (118 mL)

**INDEPENDENTLY TESTED**

**PV**

**SATISFACTION GUARANTEED**

**DO NOT USE IF PRINTED NECK BAND IS  
BROKEN OR MISSING**

If for any reason you are not satisfied with this product, please return it to the

store where purchased for a full refund.

Distributed By:  
Pharmacy Value Alliance LLC  
407 East Lancaster Avenue,  
Wayne, PA 19087

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

**BX-072**

711198

10/17

**Product Label**



Ages 2-11 years

# Children's Pain Relief

PAIN RELIEVER · FEVER REDUCER  
ACETAMINOPHEN

ORAL SUSPENSION

160 mg per 5 mL

- Alcohol Free
- Aspirin Free
- Ibuprofen Free

**Cherry Flavor**

Use **ONLY** enclosed dosage cup

4 FL OZ (118 mL)



## DO NOT USE IF PRINTED NECK BAND IS BROKEN OR MISSING

**Active ingredient (in each 5 mL = 1 teaspoonful)** 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 a 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 ■ 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:** Taking more than the

recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick

medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms. **Directions:** ■ this product does not contain directions or complete

warnings for adult use. ■ shake well before using ■ mL = milliliter; tsp = teaspoonful ■ find right dose on chart below. If possible, use weight to dose: otherwise, use age.

■ if needed, repeat dose every 4 hours while symptoms last ■ do not give more than 5

times in 24 hours ■ do not give for more than 5 days unless directed by a doctor.

| Weight (lb) | Age (yr)      | Dose (mL or tsp)* |
|-------------|---------------|-------------------|
| under 24    | under 2 years | ask a doctor      |
| 24-35       | 2-3 years     | 5 mL (1 tsp)      |
| 36-47       | 4-5 years     | 7.5 mL (1½ tsp)   |
| 48-59       | 6-8 years     | 10 mL (2 tsp)     |
| 60-71       | 9-10 years    | 12.5 mL (2½ tsp)  |
| 72-95       | 11 years      | 15 mL (3 tsp)     |

\*or as directed by a doctor

**Attention:** use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device. **Other information** ■ each 5 mL (1 tsp)

contains: sodium 3 mg ■ store between 20-25°C (68-77°F) ■ do not refrigerate

**Inactive ingredients:** anhydrous citric acid, butylparaben, FD&C red #40, flavor,

glycerin, high fructose corn syrup, microcrystalline cellulose and

carboxymethylcellulose sodium, propylene glycol, purified water, sodium

benzoate, sorbitol solution, sucralose, xanthan gum

**Questions?** Call 1-877-798-5944

**LOT:**

Distributed By: Pharmacy Value Alliance LLC

407 East Lancaster Avenue,

Wayne, PA 19087

**LR-099 EXP:**

**Premier Value**

Compare to the active ingredient in Children's TYLENOL® Oral Suspension\*\*

**Ages 2-11 years**

# Children's Pain Relief

**PAIN RELIEVER - FEVER REDUCER**  
**ACETAMINOPHEN**

**ORAL SUSPENSION**

160 mg per 5 mL

- Alcohol Free
- Aspirin Free
- Ibuprofen Free



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Distributed By:  
Pharmacy Value Alliance LLC  
407 East Lancaster Avenue,  
Wayne, PA 19087

**DO NOT USE IF PRINTED NECK BAND IS BROKEN OR MISSING**

## Drug Facts

(In each 5 mL = 1 teaspoonful)

**Active ingredient** Acetaminophen 160 mg **Purpose** Pain relief/fever reducer

**Uses** temporarily ■ reduces fever ■ relieves minor aches and pains due to: ■ the common cold ■ flu ■ headache ■ sore throat ■ toothache

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**Sore throat warning**  
If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, runny nose or vomiting, consult a doctor promptly.

**Do not use**  
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■ if your child is allergic to acetaminophen or any of the inactive ingredients in this product.

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**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**  
Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention ▶

## Drug Facts (continued)

is critical for adults as well as for children even if you do not notice any signs or symptoms.

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■ this product does not contain directions or complete warnings for adult use.  
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**ACETAMINOPHEN**

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**Use ONLY enclosed dosage cup**

**Cherry Flavor**

4 FL OZ (118 mL)




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10/17

**Premier Value® Children's Pain Relief ACETAMINOPHEN ORAL SUSPENSION Cherry Flavor**



Ages 2-11 years

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ACETAMINOPHEN

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**LOT:**

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Wayne, PA 19087

**LR-099 EXP:**



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## CHILDRENS PAIN RELIEF ORAL SUSPENSION

acetaminophen suspension

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:68016-240



**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)         |          |
| BUTYLPARABEN (UNII: 3QPI1U3FV8)                  |          |
| FD&C RED NO. 40 (UNII: WZB9127XOA)               |          |
| GLYCERIN (UNII: PDC6A3C0OX)                      |          |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)      |          |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)    |          |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)              |          |
| WATER (UNII: 059QF0KO0R)                         |          |
| SODIUM BENZOATE (UNII: OJ245FE5EU)               |          |
| SORBITOL (UNII: 506T60A25R)                      |          |
| SUCROSE (UNII: C151H8M554)                       |          |
| XANTHAN GUM (UNII: TTV12P4NEE)                   |          |

### Packaging

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:68016-240-04 | 1 in 1 CARTON   | 10/01/2018           |                    |
| 1 |                  | 118 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                                     | 10/01/2018           |                    |

**Labeler** - Pharmacy Value Alliance, LLC (101668460)

**Registrant** - AptaPharma Inc. (790523323)

### Establishment

| Name            | Address | ID/FEI    | Business Operations    |
|-----------------|---------|-----------|------------------------|
| AptaPharma Inc. |         | 790523323 | manufacture(68016-240) |

