

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

Childrens Pain Relief Oral Suspension Grape Flavor

Drug Facts

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

| 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 year | 12.5 mL (2½ 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.

Inactive ingredients anhydrous citric acid, butylparaben, D&C Red # 33, FD&C Blue # 1, 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
Grape Flavor**

**Premier
Value®**

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

Ages 2 - 11 years

Children's Pain Relief

**PAIN REDUCER - FEVER REDUCER
ACETAMINOPHEN**

ORAL SUSPENSION

160 mg per 5 mL

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

**Use ONLY enclosed
dosage cup**

Grape 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-073

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10/17

PRODUCT LABEL



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



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

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

Drug Facts

Active Ingredient Purpose
(in each 5 mL = 1 teaspoonful)
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 redness ■ 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 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 ▶

Drug Facts (continued)

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) |
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| 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
- keep carton for full directions for use.

Inactive ingredients anhydrous citric acid, butylparaben, D&C Red # 33, FD&C Blue # 1, 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 1-877-796-5944

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Children's Pain Relief

**PAIN RELIEVER - FEVER REDUCER
ACETAMINOPHEN**

ORAL SUSPENSION

Grape Flavor



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



Use **ONLY** enclosed dosage cup

Grape Flavor

4 FL. OZ. (118 mL)



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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:**

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Questions? Call 1-877-798-5944

LOT:

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

LR-100 EXP:

Premier Value Children's Pain Relief Oral Suspension Grape Flavor

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CHILDRENS PAIN RELIEF ORAL SUSPENSION

acetaminophen suspension

Product Information

| | | | | |
|--|---|---|-----------------------------|---------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68016-241 | |
| 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: 3QPIIU3FV8) | | | | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | | | | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | | | | |
| 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) | | | | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | | | | |
| XANTHAN GUM (UNII: TTV12P4NEE) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:68016-241-04 | 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 not final | part343 | 10/01/2018 | | |

Labeler - Pharmacy Value Alliance, LLC (101668460)

Registrant - Aptapharma Inc. (790523323)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------|---------|-----------|------------------------|
| Aptapharma Inc. | | 790523323 | manufacture(68016-241) |

