

INFANTS PAIN RELIEF ORAL SUSPENSION GRAPE FLAVOR- 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.

Infants' Pain Relief Oral Suspension Grape Flavor

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 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

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

■ 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

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

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

Other information

■ **each 5 ml contains:** sodium 3 mg

■ store between 20-25°C (68-77°F)

■ do not refrigerate

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[®]

Infants'

Pain Relief

PAIN RELIEVER - FEVER REDUCER

ACETAMINOPHEN

ORAL SUSPENSION

Grape Flavor

Premier

Value[®]

Compare to Infants'

TYLENOL[®] Oral Suspension

active ingredient**

Infants'

Pain Relief

PAIN RELIEVER - FEVER REDUCER

ACETAMINOPHEN

ORAL SUSPENSION

160 mg per 5 mL

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

**Use ONLY
enclosed syringe**

Grape

Flavor

2 FL OZ (59 mL)

INDEPENDENTLY TESTED

PV

SATISFACTION GUARANTEED

LOT:

EXP:

DO NOT USE IF PRINTED NECK BAND IS BROKEN OR MISSING

BX-077

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 Infants' Tylenol® Oral Suspension.**

IMPORTANT INSTRUCTIONS

1 Remove the cap.

2 Insert the syringe tip through the opening at the top of the bottle.

3 Turn the bottle upside down and fill syringe to dose.

Use enclosed syringe only.

Do not use other dosing devices.

INDEPENDENTLY TESTED

PV

SATISFACTION GUARANTEED

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

Product Label - Outer

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Drug Facts

Active ingredient (in each 5 mL) 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
- stomachache

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

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- 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

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When using this product do not exceed recommended dose (see overdose warning)

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Drug Facts (continued)

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

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■ 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.

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Other information

- each 5 mL contains: sodium 3 mg
- store between 20-25°C (68-77°F)
- do not refrigerate

Inactive ingredients

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Questions? Call weekdays from 9:30 AM to 4:30 PM EST at 1-877-788-5844

BX-077

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

**This product is not manufactured or distributed by certain consumer healthcare distributors at infants' Tylenol® Oral Suspension.



Infants' Pain Relief

PAIN RELIEVER - FEVER REDUCER

ACETAMINOPHEN

ORAL SUSPENSION

Grape Flavor



Compare to Infants' TYLENOL® Oral Suspension active ingredient**

Infants' Pain Relief

PAIN RELIEVER - FEVER REDUCER

ACETAMINOPHEN

ORAL SUSPENSION

160 mg per 5 mL

- Alcohol Free
- Aspirin Free
- Ibuprofen Free

Use ONLY enclosed syringe



Grape Flavor



2 FL OZ (59 mL)



LOT:

EXP:



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Drug Facts

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Keep out of reach of children.
Overdose warning: In case of overdose, get medical help or contact

LOT:

EXP:

Distributed By: Pharmacy Value Alliance LLC
 407 East Lancaster Avenue, Wayne, PA 19087 LR-104

PEEL HERE

Drug Facts (continued)

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Directions ■ this product does not contain directions or complete warnings for adult use. ■ shake well before using ■ mL = milliliter ■ find right dose on chart below. If possible, use weight to dose; otherwise, use age.
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Premier Value® Infants' Pain Relief

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INFANTS PAIN RELIEF ORAL SUSPENSION GRAPE FLAVOR

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-242
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: 3QP1U3FV8)
D&C RED NO. 33 (UNII: 9DBA0SBB0L)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)
GLYCERIN (UNII: PDC6A3C0OX)
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
WATER (UNII: 059QF0K00R)
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:68016-242-02	1 in 1 CARTON	10/01/2018	
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	10/01/2018	

Labeler - Pharmacy Value Alliance, LLC (101668460)

Revised: 10/2018

Pharmacy Value Alliance, LLC