

CHILDRENS PAIN RELIEF DYE-FREE- acetaminophen suspension
WinCo Foods, 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 Dye-Free Grape

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 the child takes:

- more than 5 doses in 24 hours, which is 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, or 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 contain acetaminophen, ask a doctor or pharmacist drugs.
- 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
- redness or swelling is present
- new symptoms occur
- 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. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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- 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 if you do not notice any signs or symptoms.

Directions

- **this product does not contain directions or complete warnings for adult dose**
- **do not take more than directed (see Overdose warning)**
- shake well before using
- mL = milliliter
- use only the enclosed dosing cup designed for use with this product. Do not use any other dosing device.
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give more than 5 days unless directed by a doctor

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

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

*or as directed by a doctor

Other information

- **each 5 mL contains:** sodium 2 mg
- store between 20-25°C(68-77°F)
- do not refrigerate
- see bottom panel for lot number and expiration date

Inactive ingredients

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

Questions?

Call **800-824-1706** Monday - Friday 9am - 4 pm MST

Principal Display Panel

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

ORAL SUSPENSION

Pain Relief

Children's

ACETAMINOPHEN 160 mg per 5 mL /

PAIN RELIEVER - FEVER REDUCER

Alcohol Free

Aspirin & Inuprofen Free

For Ages 2-11 Years

Dye Free

Grape Flavor

FL OZ (mL)

**This product is not manufactured or distributed by McNEIL CONSUMER HEALTHCARE, distributor of Children's TYLENOL® Oral Suspension.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY: WINCO FOODS, LLC BOISE, ID 83704

Comments or Question?

800-824-1706 www.wincofoods.com

Package label

Drug Facts (continued)

Directions

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Other information

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

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

Questions? Call 800-824-1706
Monday - Friday 9am - 4pm MST

DISTRIBUTED BY: WINCO FOODS, LLC, BOISE, ID 83704
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KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.
The Supermarket Low Price Leader®

100% SATISFACTION GUARANTEE

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

WinCo FOODS

ORAL SUSPENSION
Pain Relief

Children's

ACETAMINOPHEN
160 mg per 5 mL/
PAIN RELIEVER - FEVER REDUCER

Alcohol Free
.....
Aspirin & Ibuprofen Free
.....
For Ages 2-11 Years

Dye Free

Grape Flavor

4 FL OZ (118 mL) 160 mg per 5 mL

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Grape Flavor

4 FL OZ (118 mL) 160 mg per 5 mL

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

Drug Facts

Active Ingredient (in each 5 mL)	Purpose
Acetaminophen 160 mg	Pain reliever/fever reducer

Uses

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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

- 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

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Lot No.:
Exp. Date:

WINCO FOODS Children's Pain Relief Dye Free Grape Flavor

CHILDRENS PAIN RELIEF DYE-FREE

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-119
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: 3QPIU3FV8)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67091-119-18	1 in 1 CARTON	12/12/2014	
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	12/12/2014	

Labeler - WinCo Foods, LLC (056098817)