

INFANTS 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.

Infants Pain Relief Oral Suspension Dye-Free

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
- sore throat
- flu
- toothache
- headache

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
- **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). Ask a doctor or pharmacist before using with other drugs if you are not sure.
- 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.

Directions

- **this product does not contain directions or complete warnings for adult dose**
- **do not give more than directed (see overdose warning)**
- **shake well before use**
- use only enclosed dosing syringe
- find right dose on chart below
- remove cap and insert syringe, invert the bottle and draw the liquid to the prescribed level.
- dispense liquid slowly into child's mouth towards inner cheek
- repeat dose every 4 hours if needed
- do not give more than 5 times in 24 hours
- replace the cap tightly to maintain child resistance
- return dispenser to the box after thorough cleaning

Weight (lb)	Age (yr)	Dose (mL)*
under 24	under 2 years	ask a doctor
24-35 lbs	2-3 years	5 mL

* or as directed by a doctor

Other information

- store between 20-25°C(68-77°F)

Inactive ingredients

citric acid anhydrous, butyl paraben, flavor, glycerin, maltitol, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, propyl paraben, purified water, sucralose, xanthan gum

PDP

*Compare to the active ingredient in Childrens TYLENOL® Suspension

Infants Oral Suspension Pain relief

ACETAMINOPHEN 160 mg per 5 mL

PAIN RELIEVER-FEVER REDUCER

Alcohol Free

Aspirin & Ibuprofen Free

For Ages 2-3 Years

Dye-Free

Cherry Flavor

2 FL OZ (60 mL) 160 mg per 5 mL



INFANTS PAIN RELIEF DYE-FREE

acetaminophen suspension

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:67091-121

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: 3QP1IU3FV8)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALTITOL (UNII: D65DG142WK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM (0.7 CARBOXYMETHYL SUBSTITUTION PER SACCHARIDE; 50-100 MPAS AT 1%) (UNII: 6QM647NAYU)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67091-121-60	1 in 1 CARTON	12/12/2014	
1		60 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

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)