

DYE FREE INFANTS PAIN AND FEVER- acetaminophen suspension
FAMILY DOLLAR SERVICES INC

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.

Dye-Free Infants' Pain + Fever Drug Facts

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 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

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.**
- **do not give more than directed (see overdose warning)**
- **shake well before using**
- mL = milliliter
- find right dose on chart. If possible, use weight to dose; otherwise, use age.
- push air out of syringe. Insert syringe tip into bottle opening
- flip bottle upside down. Pull yellow part of syringe to correct dose
- dispense liquid slowly into child's mouth, toward inner cheek
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

- replace cap tightly to maintain child resistance

Dosing Chart

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

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

Other information

- **Each 5 mL contains:** sodium 2 mg
- store at room temperature

Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium, flavors, glycerin, microcrystalline cellulose, sodium benzoate, purified water, sodium citrate dihydrate, sorbitol liquid, sucralose, xanthan gum

Questions?

1-866-467-2748

PRINCIPAL DISPLAY PANEL

Compare to the active ingredient in Dye-Free Infants' Tylenol® Oral Suspension*

NDC 55319-206-02

Dye-Free

**Infants'
Pain + Fever**

Acetaminophen

Oral Suspension
Pain Reliever-Fever Reducer

Free Of:

- Dyes
- Ibuprofen
- Aspirin
- Parabens

- High Fructose Corn Syrup

Natural Grape Flavor

No Added Alcohol

Sugar Free

Use Only Enclosed Syringe

2 FL OZ (60 mL)

160 mg per 5 mL***

***Same as Children's TYLENOL

*This Product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of the registered trademark Dye-Free Infants' Tylenol® Oral Suspension.

TAMPER EVIDENT: DO NOT USE IF PRINTED SEAL OVER CAP IS BROKEN OR MISSING

IMPORTANT: Keep this carton for future reference on full labeling.



DYE FREE INFANTS PAIN AND FEVER

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-206
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)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	WHITE (Dye Free)	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-206-02	1 in 1 CARTON	05/08/2023	
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	05/08/2023	

Labeler - FAMILY DOLLAR SERVICES INC (024472631)

Revised: 9/2023

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