CHILDRENS PAIN AND FEVER- acetaminophen suspension Walgreen Company

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.

Walgreen Co. Children's Pain & Fever Drug Facts

Active ingredient (in each 5 mL = 1 teaspoon)

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

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 has ever had an allergic reaction to this product or any of its ingredients

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

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.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical 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 Liver warning)
- shake well before using
- find right dose on chart. If possible, use weight to dose; otherwise, use age.
- use only 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 for more than 5 days unless directed by a doctor

Weight (lb)	Age (yr)	Dose (tsp or mL)
under 24	under 2 years	ask a doctor
24-35	2-3 years	1 tsp or 5 mL
36-47	4-5 years	1 ½ tsp or 7.5 mL
48-59	6-8 years	2 tsp or 10 mL
60-71	9-10 years	2 ½ tsp or 12.5 mL
72-95	11 years	3 tsp or 15 mL

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

Other information

- each teaspoon contains: sodium 3 mg
- store at 20-25°C (68-77°F)
- do not use if printed neckband is broken or missing

Inactive ingredients

anhydrous citric acid, calcium sulfate, carrageenan, FD&C red #40, flavor, glycerin, high fructose corn syrup, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, propylparaben, purified water, sodium benzoate, sorbitol solution, tribasic sodium phosphate

Questions or comments?

1-800-719-9260

Principal Display Panel

children's Pain & Fever

Acetaminophen

Pain Reliever / Fever Reducer

Oral Suspension

Alcohol free

Aspirin free

Ibuprofen free

Ages 2 to 11

160 mg per 5 mL

STRAWBERRY FLAVOR

Compare to Children's Tylenol® Oral Suspension active ingredient



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Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin

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Drug Facts (continued)

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Inactive ingredients anhydrous citric acid, calcium sulfate, carrageenan, FD&C red #40, flavor, glycerin, high fructose corn syrup, hydroxyethyl callulose, and carboxymethylcellulose sodium, propylene glycol, propylparaben, purified water, sodium benzoate, sorbitol solution, tribasic sodium phosphate

(Questions or comments? 1-800-719-9260



DOSAGE CUP PROVIDED

ORG1012-F



Pain & Fever Acetaminophen Pain Reliever / Fever Reducer

VVellat Walgreens

childrens

Oral Suspension

Fever

Acetaminophen Pain Reliever / **Fever Reducer Oral Suspension**

- Alcohol free
- Aspirin free • Ibuprofen fre
- Ages 2 to 1



4 FL 0Z (118 mL) 160 mg per 5 mL

Compare to Children's Tylenol®



ITEM 480422

LOT NO.

: 75926 94 C3



& Fever

Acetaminophen Pain Reliever / **Fever Reducer Oral Suspension**

Alcohol free

• Ages 2 to 1

• Aspirin free • Ibuprofen fre



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CHILDRENS PAIN AND FEVER

acetaminophen suspension

Product Information HUMAN OTC DRUG LABEL Product Type Item Code (Source) NDC:0363-0971 Route of Administration ORAL **DEA Schedule**

Active Ingredient/Active Moiety

	Ingredient Name	Basis of Strength	Strength
ACETAMINO PHEN (ACETAMINO PHEN)		ACETAMINOPHEN	160 mg in 5 mL

Inactive Ingredients			
Ingredient Name	Strength		
FD&C RED NO. 40			
GLYCERIN			
HIGH FRUCTO SE CORN SYRUP			
CELLULO SE, MICRO CRYSTALLINE			
PROPYLENE GLYCOL			
PROPYLPARABEN			
CALCIUM SULFATE			
CARBO XYMETHYLCELLULO SE SODIUM			
WATER			
SO DIUM BENZO ATE			
SORBITOL			
SO DIUM PHO SPHATE, TRIBASIC			
ANHYDRO US CITRIC ACID			
CARRAGEENAN			

Product Characteristics			
Color	RED	Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0971-26	1 in 1 CARTON		
1		118 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	02/15/2010	

Labeler - Walgreen Company (008965063)

Revised: 3/2013 Walgreen Company