PAIN RELIEF CHILDRENS- acetaminophen liquid Western Family Foods 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.

Western Family Children's Pain Relief 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
- 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 directed (see Liver warning)
- 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 1/2 tsp or 7.5 mL
48-59	6-8 years	2 tsp or 10 mL
60-71	9-10 years	2 1/2 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, flavor, glycerin, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, propylparaben, purified water, sodium benzoate, sorbitol solution, sucralose, tribasic sodium phosphate

Package/Label Principal Display Panel

Children's PainRELIEF

ACETAMINOPHEN

Oral Suspension Liquid

Fever Reducer, Pain Reliever

Ages 2-11

Aspirin Free

Alcohol Free

Dye Free

No High Fructose Corn Syrup

Cherry flavor

Gluten Free

80 mg per $\frac{1}{2}$ teaspoon (160 mg per 5 ml)

COMPARE TO THE ACTIVE INGREDIENT OF CHILDREN'S TYELNOL® ORAL SUSPENSION









4 FL OZ (118 ml)



80 mg per 1/2 teaspoon (160 mg per 5 ml)

COMPARE TO THE ACTIVE INGREDIENT OF CHILDREN'S TYLENOL® ORAL SUSPENSION*

13388-A-PER



LOT NO.

EXP.

: 95926 3W Cl



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COMPARE TO THE ACTIVE INGREDIENT OF CHILDREN'S TYLENOL® ORAL SUSPENSION*







Drug Facts

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- 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

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Drug Facts (continued)

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Inactive ingredients anhydrous citric acid, calcium sulfate, carrageenan, flavor, glycerin, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, propylparaben, purified water, sodium benzoate, sorbitol solution, sucralose, tribasic sodium phosphate

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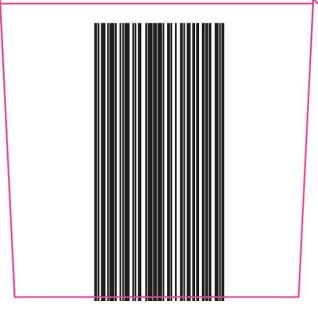
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*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Tylenol® Oral Suspension.



PAIN RELIEF CHILDRENS

acetaminophen liquid

Duadwat	Information	
Product	Intormation	

Product TypeHUMAN OTC DRUG LABELItem Code (Source)NDC:55312-959Route of AdministrationORALDEA Schedule

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthACETAMINOPHEN (ACETAMINOPHEN)ACETAMINOPHEN160 mg in 5 mL

Inactive Ingredients			
Ingredient Name	Strength		
ANHYDRO US CITRIC ACID			
CALCIUM SULFATE			
CARRAGEENAN			
GLYCERIN			
CELLULO SE, MICRO CRYSTALLINE			
CARBO XYMETHYL CELLULO SE SODIUM			
PROPYLENE GLYCOL			
PROPYLPARABEN			
WATER			
SO DIUM BENZO ATE			
SORBITOL			

SUCRALOSE	
SO DIUM PHO SPHATE, TRIBASIC	

Product Characteristics			
Color	WHITE (opaque, viscous)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:55312-959-26	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	07/11/2012	

Labeler - Western Family Foods Inc (192166072)

Revised: 10/2012 Western Family Foods Inc