CHILDRENS PAIN AND FEVER- acetaminophen suspension Best Choice (Valu Merchandisers 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.

Drug Facts

Active ingredient (in each 5 mL)

Acetaminophen 160 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily reduces fever
- temporarily relieves minor aches and pains due to:
 - the common cold
 - o flu
 - headache
 - sore throat
 - toothache

Warnings

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.

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 non-prescription). 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 dosage (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

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 you do not notice any signs or symptoms.

Directions

- this product does not contain directions or complete warnings for adult use
- do not take more than directed (see overdose warning)
- shake well before using
- find right dose on chart below. 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.
- mL = milliliter
- 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

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

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

citric acid, butylparaben, carboxymethylcellulose sodium, D&C red #33, FD&C blue #1, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

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

Children's

Pain & Fever

Acetaminophen

160 mg 5 mL

- Pain reliever/fever reducer
- Alcohol free
- Aspirin free
- Ibuprofen free

Grape flavor

For Ages 2-11

Oral suspension

FL OZ (mL)

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

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

Proudly Distributed by:

Valu Merchandisers, Co.

5000 Kansas Ave

Kansas City, KS 66106

Product Label



Drug Facts (continued) ■ use only the enclosed dosing cup designed for use with this product. Do not use any other dosing device.

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PROUDLY DISTRIBUTED BY: VALU MERCHANDISERS, CO. SOCO KANSAS AVE KANSAS CITY, KS 66106



For Ages 2 to 11 Years

COMPARE TO THE

ACTIVE INGREDIENT IN

CHILDREN'S TYLENOL



For Ages 2 to 11 Years



COMPARE TO THE ACTIVE INGREDIENT IN CHILDREN'S TYLENOL®

Children's



Acetaminophen 160 mg per 5 mL

- · Pain Reliever / Fever Reducer
- · Alcohol Free
- · Aspirin Free
- · Ibuprofen Free

GRAPE FLAVOR

Oral Suspension 4 FL 0Z (118 mL)

Children's PAIN & FEVER PAIN & FEVER



Acetaminophen 160 mg per 5 mL

- · Pain Reliever / Fever Reducer
- Alcohol Free
- Aspirin Free
- · Ibuprofen Free

GRAPE FLAVOR

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Best choice Children's Pain and Fever

CHILDRENS PAIN AND FEVER

acetaminophen suspension

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63941-288

ORAL **Route of Administration**

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D) **ACETAMINOPHEN** 160 mg in 5 mL

Inactive Ingredients Ingredient Name Strength ANHYDRO US CITRIC ACID (UNII: XF417D3PSL) **BUTYLPARABEN** (UNII: 3QPI1U3FV8) CARBO XYMETHYLCELLULO SE SODIUM (UNII: K679 OBS 311)

D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)	
WATER (UNII: 059 QF0 KO0 R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:63941-288- 04	1 in 1 BOX	02/28/2015	
1	118 mL in 1 BOTTLE, PLASTIC; 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	02/28/2015	

Labeler - Best Choice (Valu Merchandisers Company) (868703513)

Revised: 11/2015 Best Choice (Valu Merchandisers Company)