CHILDRENS PAIN AND FEVER- acetaminophen liquid Marc Glassman, 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.

Drug Facts Active ingredient

Active ingredient

(in each 5 mL = 1 teaspoonful) Acetaminophen 160 mg

Purpose

Pain reliver/fever reducer

Keep out of reach of children.

Keep out of reach of children.

Uses

temporarily reduces

- fever
- relieves minor aches and pains 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 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.

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 awway. (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.
- shake well before using
- mL = milliliter; tsp = teaspoonful
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- 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 (mL or tsp)*
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 mL (1 tsp)
36-47	4-5 years	7.5 mL (1 1/2 tsp)
48-59	6-8 years	10 mL (2 tsp)
60-71	9-10 years	12.5 mL (2 1/2 tsp)
72-95	11 years	15 mL (3 tsp)

^{*} or use as directed

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

Other information

- each 5 mL (1 tsp) contains: sodium 3 mg
- store between 20-25°C (68-77°F)
- do not refrigerate

Inactive ingredients

anhydrous citric acid, butylparaben, FD and C red # 40, flavor, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum

Marcs Childrens Pain and Fever Product Label

NDC 68998-525-24

Compare to the active ingredient in childrens Tylenol® oral suspension*

MARCS

Childrens

Pain and Fever

Pain Reliver / Fever Reducer

Acetaminophen Oral Suspension

- Alcohol-Free
- Ibuprofen Free
- Asprin Free

For Ages 2 to 11

CHERRY FLAVOR

4 FL OZ (118 mL)

160 mg per 5 mL

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

* This product is not manufactured or distributed by McNeil Consumer Healthcare, Distributer of Childrens Tylenol® Oral Suspension

Distributed by:

Marc Glassman, Inc.

West 130th Street

Cleveland, OH 44130

BX-045

LR-076

Lot:

Exp:

NDC 68998-525-24 Marcs

Children's

Pain & Fever

Pain Reliever / Fever Reducer

Acetaminophen **Oral Suspension**

For Ages 2 to 11 · Alcohol-Free

 Ibuprofen Free Aspirin Free

CHERRY FLAVOR

4 FL OZ (118 mL) 160 mg per 5 mL

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING Active ingredient (in each 5 mL = 1 teaspoontul) Pain reliever/fever reducer. Uses Temporarly reduces ■ fever ■ relieves minor aches and pains due to:

■ the common cold = flu = headache = sore throat = nothable.
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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 barmacist before use if your child is taking the blood thinning drug warfarin. When using this product do not exceed recommended dose (see overdrosse warfing) stop use and ask a doctor if w pain gets worse of lasts more than 5 days w new symptoms occur we redness or swelling is present These could be signs of a serious condition. Keep out of reach of children. Overdose warning: Taking more than the medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical aktentifun 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. A shake well before using A mL = millitler; complete warnings for adult use. A shake well before using A mL = millitler; spe = teaspoonlul A find right dose on chart below. If possible, use weight to dose: otherwise, use age. A fineded, repeat dose every 4 hours while symptoms last and one tyle more than 5 times in 24 hours A hours while symptoms last recommended dose (overdose) may cause liver damage. In case of overdose, get

ask a doctor 5 mL (1 tsp) 7.5 mL (1½ tsp) 10 mL (2 tsp) 12.5 mL (2½ tsp) 15 mL (3 tsp) Dose (mL or tsp)' under 2 years
2-3 years
4-5 years
6-8 years
9-10 years Age (yr) unless directed by a doctor 72-95 2-09

or as directed by a doctor

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Distributed by: Marc Glassman, Inc. West 130th Sreet Cleveland, OH 44130

LR-076 REV01

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DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

Drug Facts

Active ingredient (in each 5 mL = 1 teaspoorful)

Acetaminophen 160 mg......Pain reliever/fever reduce

Uses temporarily reduces ■ fever

- relieves minor aches and pains due ts:
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Drug Facts (continued)

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Other information

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Inactive ingredients anhydrous chic acid, bulybpraben, FD&C red NIO, flavor, glycerin, high frustro can ayap, nicocystaliae calubase and anborymetry loelado sodum, propilere glycol, parlied water, sodium berzoal sorbitol solution, sucralese, xanthan gum

Questions or comments: Call weekdays from 9:30 M to 4:30 PM EST at 1-877-798-5944

* Tride product is not manufactured or distributed by McNoll Consumer Healthcare, distributor of Children's Tylenol@ Oral Suspension.

Distributed by: Marc Glassman West 130th Str Cleveland, OH 44130

BX-045 REV 01

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CHILDRENS PAIN AND FEVER

acetaminophen liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68998-525
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	160 mg in 5 mL	

Inactive Ingredients			
Ingredient Name	Strength		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)			
BUTYLPARABEN (UNII: 3QPI1U3FV8)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
GLYCERIN (UNII: PDC6A3C0OX)			
HIGH FRUCTO SE CORN SYRUP (UNII: XY6 UN3QB6S)			
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)			
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SORBITOL (UNII: 506T60A25R)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
XANTHAN GUM (UNII: TTV12P4NEE)			

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

l	Packaging				
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 N	DC:68998-525-24	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/10/2014	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	10/10/2014	

Labeler - Marc Glassman, Inc. (094487477)

Revised: 9/2019 Marc Glassman, Inc.