

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 reliever/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 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.**
- **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

Marc's Children's Pain and Fever Product Label

NDC 68998-525-24

Compare to the active ingredient in children's Tylenol® oral suspension*

MARCS**Children's****Pain and Fever****Pain Reliever / Fever Reducer****Acetaminophen Oral Suspension**

- **Alcohol-Free**
- **Ibuprofen Free**
- **Aspirin 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, Distributor of Children's Tylenol® Oral Suspension

Distributed by:

Marc Glassman, Inc.

West 130th Street

Cleveland, OH 44130

BX-045

LR-076

Lot:

Exp:

NDC 68998-525-24

Compare to the active ingredient
in children's Tylenol® oral suspension***Marc's**

Children's

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

- Alcohol-Free
- Ibuprofen Free
- Aspirin 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**
*Active ingredient (in each 5 mL = 1 teaspoonful)**Pain reliever/fever reducer*
Acetaminophen 160 mg.....*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 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 a 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 ■ new symptoms occur ■ 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 recommended dose (overdose) may cause liver damage. 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. ■ 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 (1½ tsp)
48-59	6-8 years	10 mL (2 tsp)
60-71	9-10 years	12.5 mL (2½ tsp)
72-95	11 years	15 mL (3 tsp)

*or as directed by a doctor

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&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**Lot:**Distributed by:
Marc Glassman, Inc.
West 130th Street
Cleveland, OH 44130

LR-076 REV01

Exp:

DO NOT USE IF PRINTED NECKBAND IS
BROKEN OR MISSING

Drug Facts

Active ingredient **Purpose**
(In each 5 mL = 1 teaspoonful)
Acetaminophen 160 mg.....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 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

Taking more than the recommended dose (overdose) may cause ▶

Drug Facts (continued)

Liver damage. 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.**
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■ mL = milliliter; tsp = teaspoonful
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48-59	6-8 years	10 mL (2 tsp)
60-71	9-10 years	12.5 mL (2½ tsp)
72-85	11 years	15 mL (3 tsp)

*or as directed by a doctor

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&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

Questions or comments: Call weekdays from 9:30 AM to 4:30 PM EST at 1-877-798-5844.

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

Distributed by:
Marc's Glassman, Inc.
West 130th Street
Cleveland, OH 44130

BX-045 REV 01

Marc's

Children's

Pain & Fever

Pain Reliever / Fever Reducer

NDC 68998-525-24

Compare to the active ingredient in children's Tylenol® oral suspension

Marc's

Children's

Pain & Fever

Pain Reliever / Fever Reducer

Acetaminophen
Oral Suspension

- Alcohol-Free
- Ibuprofen Free
- Aspirin Free

For Ages 2 to 11

CHERRY FLAVOR

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



NDC 68998-525-24

Compare to the active ingredient in children's Tylenol® oral suspension

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Pain & Fever

Pain Reliever / Fever Reducer

Acetaminophen
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CHERRY FLAVOR

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



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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
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)			ACETAMINOPHEN	160 mg in 5 mL
Inactive Ingredients				
Ingredient Name			Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
BUTYLPARABEN (UNII: 3QPI1U3FV8)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
GLYCERIN (UNII: PDC6A3C0OX)				
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)				
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				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC: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)