

# **CHILDREN ACETAMINOPHEN ORAL SOLUTION- acetaminophen liquid MAJOR PHARMACEUTICALS**

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**Major- APAP Child Sol 7014**

## **Active ingredient (per 5 mL teaspoonful)**

Acetaminophen 160 mg

## **Purpose**

Pain Reliever/Fever Reducer

## **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 a 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 before use if your child is** taking the blood thinning drug warfarin.

**When using this product: Do not exceed recommended dose.**

## **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.

## **Uses**

- temporarily relieves minor aches and pains due to:
- headache

- toothache
- the common cold
- temporarily reduces fever
- flu
- sore throat

**If pregnant or breast-feeding, ask a health professional before use**

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults/children even if you do not notice any signs or symptoms.

**Directions**

- **do not take more than directed**
- find dose in chart below
- if possible, use weight to dose, otherwise use age
- dosage may be repeated every 4 hours, or as directed by a doctor
- do not give more than 5 doses in 24 hours

Weight (lbs)	under 24	24-35	36-47	48-59	60-71	72-95
Age (years)	under 2	2 to 3	4 to 5	6 to 8	9 to 10	11
Dosage	consult	1 tsp (5	1 1/2 tsp	2 tsp (10	2 1/2 tsp	3 tsp (15
Teaspoonful (tsp)	Physician	mL)	(7.5 mL)	mL)	(12.5 mL)	mL)

**Inactive ingredients:** artificial and natural cherry flavor, citric acid, FD&C Red #40, methylparaben, polyethylene glycol, propylene glycol, propylparaben, purified water, sodium citrate, sucralose

**Drug Facts**

**Active Ingredient (in each 5 mL)** **Purpose**

Acetaminophen 160 mg Pain Reliever/Fever Reducer

**Uses** ■ temporarily relieves minor aches and pains due to ■ headache ■ toothache ■ the common cold ■ temporarily reduces fever ■ flu ■ sore throat

**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 a 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 before use if your child is taking the blood thinning drug warfarin.**

**When using this product: Do not exceed recommended dose.**

**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. ▶

**MAJOR**® NDC 0904-7014-20

compare to the active ingredient of Children's Tylenol®\*

**children's acetaminophen oral solution**

**acetaminophen liquid 160 mg per 5 mL**

**pain reliever/fever reducer**

alcohol free  
aspirin free



cherry flavor

**Ages 2 - 11 years**

**4 FL OZ (118 mL)**

**Drug Facts (continued)**

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults/children even if you do not notice any signs or symptoms.

**Directions** ■ do not take more than directed

■ mL = milliliters ■ do not use any other dosing device ■ find dose in chart below ■ if possible, use weight to dose, otherwise use age ■ dosage may be repeated every 4 hours or as directed by a doctor ■ do not give more than 5 doses in 24 hours

Weight (lbs)	under 24	24-35	36-47	48-59	60-71	72-95
Age (years)	Under 2	2 to 3	4 to 5	6 to 8	9 to 10	11
Dosage	consult	1 tsp	1 1/2 tsp	2 tsp	2 1/2 tsp	3 tsp
Teaspoonful (tsp)	Physician	(5 mL)	(7.5 mL)	(10 mL)	(12.5 mL)	(15 mL)

**Other information**

■ store at room temperature 20°C to 25°C (68°F-77°F). Permitted excursions between 15°C to 30°C (59°F-86°F).

■ protect from freezing ■ protect from light

■ **TAMPER-EVIDENT:** Do not use if foil seal over bottle opening is torn, broken, or missing.

■ Pharmacist-Preserve and dispense in tight, light-resistant containers with a child resistant cap as defined in the USP

**Inactive Ingredients:** artificial and natural cherry flavor, citric acid, FD&C Red #40, methylparaben, polyethylene glycol, propylene glycol, propylparaben, purified water, sodium citrate, sucralose.

**Questions or comments?** 800-616-2471

\*This product is not manufactured or distributed by the owner of the registered trademark Children's Tylenol®

Rev. 06/25 M-164 Re-order No. 701198



Distributed by: **MAJOR PHARMACEUTICALS**  
Indianapolis, IN 46268  
(800) 616-2471  
www.major-rugby.com  
L-156

Lot #: \_\_\_\_\_  
Exp Date: \_\_\_\_\_

**Drug Facts****Active Ingredient (in each 5 mL)** **Purpose**

Acetaminophen 160 mg ..... Pain Reliever/Fever Reducer

**Uses** ■ temporarily relieves minor aches and pains due to ■ headache ■ toothache ■ the common cold ■ temporarily reduces fever ■ flu ■ sore throat**Warnings****Liver Warning:** This product contains acetaminophen. Severe liver damage may occur if your child takes

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■ with other drugs containing acetaminophen

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■ skin reddening ■ blisters ■ rash

If a 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 before use if your child is taking the blood thinning drug warfarin.****When using this product: Do not exceed recommended dose.****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. ▶Distributed by:  
MAJOR\* PHARMACEUTICALS  
Indianapolis, IN 46268  
(800) 616-2471  
www.major-rugby.com  
L-157

Lot #:

Exp Date:

**MAJOR**<sup>®</sup>

NDC 0904-7014-16

compare to the active  
ingredient of  
Children's Tylenol\* \***children's  
acetaminophen  
oral solution****acetaminophen liquid  
160 mg per 5 mL  
pain reliever/fever reducer**alcohol free  
aspirin free

cherry flavor

ages 2 -11 years  
**16 fl oz (473 mL)****Drug Facts (continued)****Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults/children even if you do not notice any signs or symptoms.**Directions** ■ do not take more than directed

■ mL = milliliters ■ do not use any other dosing device ■ find dose in chart below

■ if possible, use weight to dose, otherwise use age ■ dosage may be repeated every 4 hours, or as directed by a doctor ■ do not give more than 5 doses in 24 hours

Weight (lbs)	under 24	24-35	36-47	48-59	60-71	72-95
Age (years)	Under 2	2 to 3	4 to 5	6 to 8	9 to 10	11
Dosage Teaspoonful (tsp)	consult Physician	1 tsp (5 mL)	1 ½ tsp (7.5 mL)	2 tsp (10 mL)	2 ½ tsp (12.5 mL)	3 tsp (15 mL)

**Other information**

■ store at room temperature 20°C to 25°C (68°F-77°F). Permitted excursions between 15°C to 30°C (59°F-86°F).

■ protect from freezing ■ protect from light

■ **TAMPER-EVIDENT:** Do not use if foil seal over bottle opening is torn, broken, or missing.

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Rev. 06/25 M-164 Re-order No. 701199**CHILDREN ACETAMINOPHEN ORAL SOLUTION**

acetaminophen liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-7014
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX25C1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

<b>1</b>	NDC:0904-7014-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2019	
<b>2</b>	NDC:0904-7014-20	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	10/01/2019	

**Labeler** - MAJOR PHARMACEUTICALS (191427277)

Revised: 6/2025

MAJOR PHARMACEUTICALS