CHILDRENS ACETAMINOPHEN- acetaminophen suspension Major Pharmaceuticals

Major Pharmaceuticals Children's Acetaminophen 160 mg / 5 mL Drug Facts

Active ingredient (in each 5 mL)

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

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 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

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: 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
- do not give more than directed (see overdose warning)
- shake well before using
- mL = milliliter
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- remove the child protective cap and squeeze your child's dose into the dosing cup
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

Weight (lb)	Age (yr)	Dose (mL)*
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 mL
36-47	4-5 years	7.5 mL
48-59	6-8 years	10 mL
60-71	9-10 years	12.5 mL

	-	
72-95	11 years	15 mL

^{*}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 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, purified water, sodium benzoate, sorbitol solution, sucralose, tribasic sodium phosphate

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

MAJOR®

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

Children's Acetaminophen 160 mg/5 mL Oral Suspension

Pain Reliever / Fever Reducer

For Ages 2-11 Years

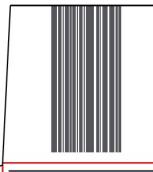
- Paraben Free
- Alcohol Free
- Aspirin Free
- Ibuprofen Free

Fast, effective relief of children's pain and fever

Dye-Free

Cherry Flavor

4 FL OZ (118 mL)



Drug Facts

Active ingredient (in each 5 mL)

Purpose

- Uses temporarily:
 reduces fever
 relieves minor aches and pains due to:
 the common cold
 the common cold
 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
- dally amount
 with other drugs containing acetaminophen
 Allergy alert: Acetaminophen may cause severe skin
 reactions. Symptoms may include:
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 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

- 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

When using this product do not exceed recommended dose (see overdose warning)

Stop use and ask a doctor if

- Stop use and ask a doctor if
 mean 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
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Drug Facts (continued)

Directions

- this product does not contain directions or complete warnings for adult use

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- warning)

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 to dose; otherwise, use age.
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 child's dose into the dosing cup
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Weight (lb)	Age (yr)	Dose (mL)*
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48-59	6-8 years	10 mL
60-71	9-10 years	12.5 mL
72-05	11 years	15 ml

*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 6 mL contains: sodium 3 mg
 store at 20-25°C (68-77°F)
 do not use if printed neckband is broken or

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

Questions or comments? 1.800.719.9260

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

Distributed by: MAJOR® PHARMACEUTICALS Indianapolis, IN 46268 (800) 616-2471 www.majorpharmaceuticals.com

MAJOR[®]

NDC 0904-7445-20 Compare to the active ingredient in Children's Tylenol® Oral Suspension**

Children's Acetaminophen 160 mg/5 mL

Oral Suspension

Pain Reliever / Fever Reducer

For Ages 2-11 Years

- Paraben Free
- Alcohol Free
- Aspirin Free
- Ibuprofen Free

Fast, effective relief of children's pain and fever



Dye-Free **Cherry Flavor**

4 FL OZ (118 mL)



Children's Acetaminophen 160 mg/5 mL

Oral Suspension

Pain Reliever / Fever Reducer

DIRECTIONS: Shake well before using



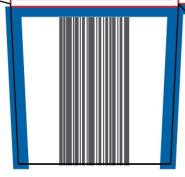
STEP 2. Remove child protective cap



STEP 3. Squeeze your child's dose into the dosing cup



Please see dosing chart or ask a doctor for your child's correct dose





CHILDRENS ACETAMINOPHEN

acetaminophen suspension

Product Information

Route of Administration

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:0904-7445

ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	160 mg in 5 mL	

Inactive Ingredients			
Ingredient Name	Strength		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
CALCIUM SULFATE, UNSPECIFIED FORM (UNII: WATODDB505)			
CARRAGEENAN (UNII: 5C69YCD2YJ)			
GLYCERIN (UNII: PDC6A3C0OX)			
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SORBITOL (UNII: 506T60A25R)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X)			

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:0904-7445- 20	1 in 1 CARTON	03/22/2024		
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	03/22/2024	

Labeler - Major Pharmaceuticals (191427277)

Revised: 4/2024 Major Pharmaceuticals