

**ACETAMINOPHEN- acetaminophen solution**  
**Major Pharmaceuticals**

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**Acetaminophen Oral Solution USP - Major**

***Active ingredient(s)***

***(in each 5 mL teaspoonful)***

**Acetaminophen** 160 mg .....Pain reliever/fever reducer

***Purpose***

Pain reliever/fever reducer

***Uses***

temporarily relieves minor aches and pains due to:

- headache
- muscular aches
- backache
- minor pain of arthritis
- the common cold
- toothache
- premenstrual and menstrual cramps

temporarily reduces fever

***Warnings***

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if:

- adult takes more than 6 doses in 24 hours, which is the maximum daily amount
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

**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.
- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor
- if you are allergic to acetaminophen or any of the inactive ingredients of this product

Ask a doctor before use if the user has liver disease

Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin

**Stop use and ask a doctor if**

- symptoms do not improve
- new symptoms occur
- pain or fever persists or gets worse

**If pregnant or breast-feeding,**

ask a health professional before use.

**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 children even if you do not notice any signs or symptoms.

**Directions**

- **do not take more than directed (see overdose warning)**

age	dose
adults and children 12 years of age and over	20.3 mL (650 mg) every 4 to 6 hours not to exceed 6 doses in a 24-hour period
children 6 to under 12 years of age	10.15 mL (325 mg) every 4 hours not to exceed 5 doses in a

	24-hour period
children 4 to under 6 years of age	7.5 mL (240 mg) every 4 hours not to exceed 5 doses in a 24-hour period
children 2 to under 4 years of age	5 mL (160 mg) every 4 hours not to exceed 5 doses in a 24-hour period
children under 2 years of age	consult a doctor

### ***Other information***

- **Each 5 mL contains:** sodium 2 mg
- store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]
- keep tightly closed ■ protect from light
- a red, cherry flavored solution supplied in the following oral dosage forms:

NDC 0904-7319-41: 5 mL unit dose cup, in a tray of ten cups.

NDC 0904-7320-02: 10.15 mL unit dose cup, in a tray of ten cups.

NDC 0904-7321-03: 20.3 mL unit dose cup, in a tray of ten cups.

### ***Inactive ingredients***

Citric acid, FD&C Red No. 40, flavoring, glycerin, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol and sucrose.

### ***Questions or comments?***

Call 1-800-845-8210. You may also report serious side effects to this phone number.

R11/22

### **Distributed by:**

**MAJOR® PHARMACEUTICALS**  
**Indianapolis, IN 46268**

### **PRINCIPAL DISPLAY PANEL - 5 mL Unit Dose Cup**

**MAJOR®**

NDC 0904-7319-41

**Acetaminophen Oral Solution USP**

**160 mg/ 5 mL**

**ALCOHOL FREE**

**Delivers 5 mL • See insert**

**For Institutional Use Only**

MAJOR® PHARMACEUTICALS  
Indianapolis, IN 46268

F0657C051022



**PRINCIPAL DISPLAY PANEL - 10.15 mL Unit Dose Cup**

**MAJOR®**

NDC 0904-7320-02

**Acetaminophen Oral Solution USP**

**325 mg/ 10.15 mL**

**Alcohol Free**

**Delivers 10.15 mL • See insert**

**For Institutional Use Only**

MAJOR<sup>®</sup> PHARMACEUTICALS  
Indianapolis, IN 46268

F0657C111022



**PRINCIPAL DISPLAY PANEL - 20.3 mL Unit Dose Cup**

**MAJOR<sup>®</sup>**

NDC 0904-7321-03

**Acetaminophen Oral Solution USP**

**650 mg/ 20.3 mL**

**Alcohol Free**

**Delivers 20.3 mL • See insert**

**For Institutional Use Only**

MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268

F0657C211022



## ACETAMINOPHEN

acetaminophen solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-7319(NDC:0121-0657)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	160 mg in 5 mL	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				
SORBITOL (UNII: 506T60A25R)				
SUCROSE (UNII: C151H8M554)				
<b>Product Characteristics</b>				
Color	red ((clear, red liquid))	Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7319-70	10 in 1 CASE	06/05/2023	
1		10 in 1 TRAY		
1	NDC:0904-7319-41	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M013	06/05/2023		

## ACETAMINOPHEN

acetaminophen solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-7320
Route of Administration	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 10.15 mL

**Inactive Ingredients**

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K0OR)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	

**Product Characteristics**

Color	red	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7320-71	10 in 1 CASE	06/05/2023	
1		10 in 1 TRAY		
1	NDC:0904-7320-02	10.15 mL in 1 CUP, UNIT-DOSE; 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	06/05/2023	

**ACETAMINOPHEN**

acetaminophen solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-7321
<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	650 mg in 20.3 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCROSE</b> (UNII: C151H8M554)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7321-76	10 in 1 CASE	06/05/2023	
1		10 in 1 TRAY		
1	NDC:0904-7321-03	20.3 mL in 1 CUP, UNIT-DOSE; 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	06/05/2023	

