ACETAMINOPHEN- acetaminophen solution
Major Pharmaceuticals

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.

Acetaminophen Oral Solution USP - Major

Active ingredient(s)

(in each 5 mL teaspoonful)

Acetaminophen 160 mg

Purpose

Pain reliever/fever reducer

Use(s)

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.

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®PHARMACEUTICALS
Indianapolis, IN 46268

F0657C111022

PRINCIPAL DISPLAY PANEL - 20.3 mL Unit Dose Cup

MAJOR®

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			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-7319(NDC:0121-0657)
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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	red ((clear, red liquid))	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	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: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
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 not final	part343	06/05/2023	

ACETAMINOPHEN

acetaminophen solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-7321
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
	Basis of	

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20.3 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: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
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:0904-7321-76	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 not final	part343	06/05/2023	

Labeler - Major Pharmaceuticals (191427277)

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