

**ACETAMINOPHEN- acetaminophen tablet, coated**  
**RETAIL BUSINESS SERVICES , LLC.**

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**1170-CAR-2024-0614**

***Drug Facts***

**Active ingredient (in each gelcap)**

Acetaminophen 500 mg

**Purpose**

Pain reliever/fever reducer

**Uses**

- temporarily relieves minor aches and pains due to:
  - the common cold
  - headache
  - backache
  - minor pain of arthritis
  - toothache
  - muscular aches
  - premenstrual and menstrual cramps
- temporarily reduces fever

**Warnings**

**Liver warning**

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 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.

**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 you are allergic to acetaminophen or any of the inactive ingredients in this product

**Ask a doctor before use if you have** liver disease.

**Ask a doctor or pharmacist before use if you are** taking the blood thinning drug warfarin

**Stop use and ask a doctor if**

- pain gets worse or lasts more than 10 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.

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

**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 for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

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

adults and children 12 years and over	<ul style="list-style-type: none"><li>▪ take 2 gelcaps every 6 hours while symptoms last</li><li>▪ do not take more than 6 gelcaps in 24 hours, unless directed by a doctor</li><li>▪ do not use for more than 10 days unless directed by a doctor</li></ul>
children under 12 years	<ul style="list-style-type: none"><li>▪ ask a doctor</li></ul>

**Other information**

- store between 20-25°C (68-77°F)
- retain carton for complete product information

**Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, D&C red #33, edible ink, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol, povidone,

pregelatinized starch, stearic acid, titanium dioxide

**PRINCIPAL DISPLAY PANEL**

CAREone®

NDC 72476-070-03

Compare to the active ingredient in Tylenol® Extra Strength Rapid Release Gels†  
Extra Strength

ACETAMINOPHEN

Pain Reliever / Fever Reducer

For adults

Actual Size

100 GELCAPS

500 mg EACH



## ACETAMINOPHEN

acetaminophen tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72476-070
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

### Inactive Ingredients

Ingredient Name	Strength

<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)
<b>GELATIN</b> (UNII: 2G86QN327L)
<b>HYDROXYPROPYL CELLULOSE (1600000 WAMW)</b> (UNII: RFW2ET671P)
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)
<b>POVIDONE</b> (UNII: FZ989GH94E)
<b>STARCH, PREGELATINIZED CORN</b> (UNII: O8232NY3SJ)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)

### Product Characteristics

<b>Color</b>	gray (red and light blue ends)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	G1
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-070-03	1 in 1 CARTON	03/01/2024	
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:72476-070-13	225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	03/01/2024	

**Labeler** - RETAIL BUSINESS SERVICES , LLC. (967989935)