

**ACETAMINOPHEN- acetaminophen tablet**  
**PUBLIX SUPERMARKETS, INC**

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**Extra Strength**  
**Pain Relief**

**Rapid Release**

**ACETAMINOPHEN, 500 mg**

- **Pain reliever/fever reducer**
- **For adults**
- **Contains no aspirin**

**Active ingredient (in each gelcap)**

Acetaminophen USP, 500 mg

**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

**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

take 2 gelcaps every 6 hours while symptoms last

do not take more than 6 gelcaps in 24 hours, unless directed by a doctor

□ do not use for more than 10 days unless directed by a doctor  
children under 12 years

□ ask a doctor

### **Other information**

□ store at 20-25°C (68-77°F). See USP Controlled Room Temperature

□ avoid high humidity

□ see end panel for expiration date and lot number

### **Inactive ingredients**

ammonium hydroxide, black iron oxide, colloidal silicon dioxide, croscarmellose sodium, D&C red #33, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide red, isopropyl alcohol, n-butyl alcohol, polyethylene glycol, povidone k-30, pregelatinized starch, propylene glycol, shellac glaze, stearic acid, titanium dioxide, yellow iron oxide

### **Questions or comments?**

call **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST

### **Principal display panel**

COATING  
FREE AREA

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**Drug Facts (continued)**

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)

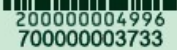
- |                                       |  |
|---------------------------------------|--|
| adults and children 12 years and over | ■ take 2 gelcaps every 6 hours while symptoms last                         |
|                                       | ■ do not take more than 6 gelcaps in 24 hours, unless directed by a doctor |
| children under 12 years               | ■ do not use for more than 10 days unless directed by a doctor             |

**ask a doctor**

**Other information**

- store at 20-25°C (68-77°F). See USP Controlled Room Temperature.
- avoid high humidity
- see and panel for expiration date and lot number

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COATING  
FREE AREA

**Extra Strength  
Rapid Release  
Pain Relief**  
ACETAMINOPHEN, 500 mg

- Pain reliever/fever reducer
- For adults
- Contains no aspirin

NDC 41415-167-05

**Extra Strength  
Rapid Release  
Pain Relief**  
ACETAMINOPHEN, 500 mg

- Pain reliever/fever reducer
- For adults
- Contains no aspirin



ACTUAL SIZE

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

**50** Gelcaps



Lot  
Exp.

COATING  
FREE AREA

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

TAMPER EVIDENT: DO NOT USE IF UNPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

**Drug Facts**

**Active ingredient (in each gelcap)** Purpose  
Acetaminophen USP, 500 mg. 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 you take

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- 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 redness ■ hives ■ 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



# ACETAMINOPHEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41415-167
Route of Administration	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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
HYDROXYMETHYL CELLULOSE (UNII: 273FM27VK1)			
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)			

<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)
<b>HYPROMELLOSE 2910 (3 MPA.S)</b> (UNII: 0VUT3PMY82)
<b>POVIDONE K30</b> (UNII: U725QWY32X)
<b>AMMONIA</b> (UNII: 5138Q19F1X)
<b>SHELLAC</b> (UNII: 46N107B71O)
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)
<b>GELATIN</b> (UNII: 2G86QN327L)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)
<b>HYDROXYPROPYL CELLULOSE (1600000 WAMW)</b> (UNII: RFW2ET671P)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)

### Product Characteristics

<b>Color</b>	gray (Encapsulated with red opaque and blue gray opaque hard gelatin shells)	<b>Score</b>	2 pieces
<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:41415-167-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2024	
2	NDC:41415-167-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/27/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	08/27/2024	

**Labeler** - PUBLIX SUPERMARKETS, INC (006922009)