

ACETAMINOPHEN- acetaminophen tablet
PUBLIX SUPERMARKETS, INC

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



READ AND KEEP CARTON FOR COMPLETE
WARNINGS AND INFORMATION

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

Drug Facts

Active ingredient (in each gelcap) 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:
 - 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 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
- 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

Drug Facts (continued)

Keep out of reach of children
Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away: (1-800-222-4222). 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 and 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, polyvinylpyrrolidone K-30, pregelatinized starch, propylene glycol, stearic acid, 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

*This product is not manufactured or distributed by Kenue Inc., owner of the registered trademark Extra Strength Tylenol® Rapid Release Gels.

DISTRIBUTED BY
PUBLIX SUPER MARKETS, INC.,
3300 PUBLIX CORPORATE PARKWAY,
LAKELAND, FL 33811
1-888-267-3037 publix.com
PUBLIX GUARANTEE: COMPLETE
SATISFACTION OR YOUR MONEY BACK



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

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

NDC 41415-167-10

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

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



ACTUAL SIZE

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

100 Gelcaps



Publix.

Lot
Exp.

COATING
FREE AREA

NDC 41415-167-10

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

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



ACTUAL SIZE

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

100 Gelcaps

COATING



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

Product Characteristics

Color	gray (Encapsulated with red opaque and blue gray opaque hard gelatin shells)	Score	2 pieces
Shape	OVAL	Size	19mm
Flavor		Imprint Code	G1
Contains			

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)

