

**ACETAMINOPHEN- acetaminophen tablet**  
**TOPCO ASSOCIATES LLC**

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**EXTRA STRENGTH**

**Pain Relief**

**ACETAMINOPHEN USP, 500 mg - PAIN RELIEVER / FEVER REDUCER**  
**RAPID RELEASE**

**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**

### **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

Drug Facts (continued)

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)
- 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, isopropyl alcohol, n-butyl alcohol, polyethylene glycol, povidone k-30, pregelatinized starch, propylene glycol, red iron oxide, 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**





NDC 36800-665-40

EXTRA STRENGTH

# Pain Relief

ACETAMINOPHEN USP, 500 mg  
PAIN RELIEVER / FEVER REDUCER

RAPID RELEASE

For Adults

400 GELCAPS



\*COMPARE TO THE ACTIVE INGREDIENT IN EXTRA STRENGTH TYLENOL® RAPID RELEASE GELS

READ THE DIRECTIONS AND WARNINGS BEFORE USE  
TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

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 Call 1-877-770-4983 Mon-Fri 8:00 AM EST to 5:00 PM PST

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

Contains No Aspirin

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COATING FREE AREA

200000004823  
700000003624

IMPORTANT: READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

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**EXTRA STRENGTH**

**TopCare health**

**Pain Relief**

ACETAMINOPHEN USP, 500 mg - PAIN RELIEVER / FEVER REDUCER

RAPID RELEASE

100 GELCAPS

For Adults

actual size

\*COMPARE TO THE ACTIVE INGREDIENT IN EXTRA STRENGTH TYLENOL® RAPID RELEASE GELS

NDC 36800-665-10

COATING FREE AREA

0 36800 19991 0

Lot Exp.

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Lot Exp.

# ACETAMINOPHEN

acetaminophen tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-665
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>BUTYL ALCOHOL</b> (UNII: 8PJ61P6TS3)	
<b>HYDROXYPROPYL CELLULOSE (1600000 WAMW)</b> (UNII: RFW2ET671P)	
<b>HYDROXYMETHYL CELLULOSE</b> (UNII: 273FM27VK1)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>HYPROMELLOSE 2910 (3 MPA.S)</b> (UNII: 0VUT3PMY82)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>FERROSOFERRIC 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

		<b>Marketing Start</b>	<b>Marketing End</b>
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-665-21	225 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2024	
2	NDC:36800-665-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2024	
3	NDC:36800-665-40	400 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	10/14/2024	

**Labeler** - TOPCO ASSOCIATES LLC (006935977)

Revised: 12/2025

TOPCO ASSOCIATES LLC