

**ACETAMINOPHEN 500 MG- acetaminophen tablet**  
**Pioneer Life Sciences, LLC**

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**Extra Strength ACETAMINOPHEN 500 MG Caplet**

***Drug Facts***

***Active ingredient (in each caplet)***

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
- muscular aches
- 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 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 ingredient in this product.

**Ask a doctor before use if you have**

- liver disease

**Ask a doctor/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
- redness or swelling is present
- new symptoms occur

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 (1-800-222-1222) right away. 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 Caplets every 6 hours while symptoms last
- do not take more than 6 caplets in 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)

**Inactive ingredients**

Croscarmellose Sodium, Lactose Monohydrate, Magnesium Stearate, Polyethylene Glycol, Polyvinyl Alcohol, Povidone k30, Purified water, Sodium Starch Glycolate, Starch Corn, Talc, Titanium Dioxide

**Questions or comments?**

Call +1 (732) 994-2808 or email support@gencare.health

**TAMPER EVIDENT: Do not use if imprinted safety seal under cap is broken or**

missing.

This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division., owner of the registered trademark Tylenol® Extra Strength Caplets.

**Distributed by:**

**GenCare Consumer Products LLC**

40E Cotters Ln Suite A,

East Brunswick, NJ 08816

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<b>Drug Facts</b>	<p><b>Purpose</b> Pain reliever/fever reducer</p> <p><b>Active ingredients (in each caplet)</b> Acetaminophen 500 mg ..... Pain reliever/fever reducer</p> <p><b>Uses:</b> ■ temporarily relieves minor aches and pains due to: ■ the common cold ■ headache ■ backache ■ minor pain or arthritis ■ muscular aches ■ toothache ■ menstrual and menstrual cramps ■ temporarily reduces fever</p> <p><b>Warnings: Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take more than 4,000 mg of acetaminophen in 24 hours with other drug containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product. <b>Allergy Alert:</b> 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.</p> <p><b>Do not use</b> ■ with any 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.</p> <p><b>Ask a doctor before use if you have:</b> ■ liver disease</p> <p><b>Ask a doctor/ pharmacist before use if you are</b> ■ 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 ■ redness or swelling is present ■ new symptoms occur. These could be signs of a serious condition.</p> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use. <b>KEEP OUT OF REACH OF CHILDREN. Overdose Warning:</b> In case of overdose, get medical help or contact Poison Control (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p> <p><b>Directions:</b> ■ do not take more than directed (see overdose warning) ■ Adults and children 12 years and over: ■ take 2 caplets every 6 hours while symptoms last ■ do not take more than 6 caplets 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</p> <p><b>Other information:</b> ■ store between 20°-25°C (68°-77°F)</p> <p><b>Inactive Ingredients:</b> Croscarmellose Sodium, Lactose Monohydrate, Magnesium Stearate, Polyethylene Glycol, Polyvinyl Alcohol, Povidone K30, Purified Water, Sodium Starch Glycolate, Starch Corn, Talc, Titanium Dioxide</p> <p><b>Questions or Comments?</b> Call +1 (732) 994-2808 or email support@gencare.health</p>
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Lot No. Exp. Dt.

PL0218-00

## ACETAMINOPHEN 500 MG

acetaminophen tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72090-008
<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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	

<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)
<b>POVIDONE K30</b> (UNII: U725QWY32X)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)
<b>TALC</b> (UNII: 7SEV7J4R1U)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	capsule	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	P500
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72090-008-01	500 in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2024	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	06/11/2024	

**Labeler** - Pioneer Life Sciences, LLC (014092742)