

ACETAMINOPHEN 500 MG- acetaminophen tablet
Pioneer Life Sciences, LLC

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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Do not use ■ 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.

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.
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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 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 between 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

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Distributed by: GenCare Consumer Products LLC., East Brunswick, NJ www.gencare.health
PL0218-00

ACETAMINOPHEN 500 MG

acetaminophen tablet

Product Information

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

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

Product Characteristics

Color	white	Score	no score
Shape	capsule	Size	18mm
Flavor		Imprint Code	P500
Contains			

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)