

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 **1-732-698-5070** Monday through friday 9 AM to 5 pm EST or
www.pioneerlifesciences.com

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

NDC 72090-008-30 (300 tablets in a bottle)

†compare to Tylenol® Extra Strength Caplets active ingredients

Pain Relief

pain reliever/fever reducer

EXTRA STRENGTH ACETAMINOPHEN
500mg each caplet

300 caplets for adults
not actual size

TAMPER EVIDENT

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Drug Facts	
Active ingredients (in each caplet) Acetaminophen 500 mg	Purpose Pain reliever/fever reducer
Uses: temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> ■ 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 drug containing acetaminophen or 3 or more alcoholic drinks every day while using this product. Allergy Alert: Acetaminophen may cause severe skin reactions. Symptoms may include: skin redness, blisters, rash. If a skin reaction occurs, stop use and seek medical help right away. 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	
Stop use and ask a doctor if: <ul style="list-style-type: none"> ■ 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. 	
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 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) <ul style="list-style-type: none"> ■ 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: <ul style="list-style-type: none"> ■ 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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Lot No. Exp. Dt.
3 72090 100049 0

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

CROSCARMELLOSE 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:72090-008-30	300 in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	05/11/2023	

Labeler - Pioneer Life Sciences, LLC (014092742)