

ACETAMINOPHEN 500 MG- acetaminophen tablet
Pioneer Life Sciences, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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 Do not use if imprinted safety seal under cap is broken or missing.

Drug Facts

Active ingredients (in each caplet)
Acetaminophen 500 mg 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 drug 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 ■ 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

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 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.

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■ 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, Sarcosyl, Talc, Titanium Dioxide

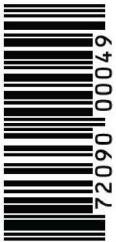
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Distributed by:
GenCare Consumer Products LLC
40E Cotters Ln Suite A,
East Brunswick, NJ 08816

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	
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 not final	part343	05/11/2023	

Labeler - Pioneer Life Sciences, LLC (014092742)

Registrant - Pioneer Life Sciences, LLC (014092742)