EXTRA STRENGTH ACETAMINOPHEN- acetaminophen tablet, film coated Strategic Sourcing Services, LLC

EXTRA STRENGTH PAIN RELIEVER CAPLETS

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
 - toothache
 - muscular aches
 - 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 ingredients in this product

Ask a doctor before use if you have liver disease

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

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 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)
- do not use if carton is opened or inner Safety Seal is broken or missing

Inactive ingredients

hypermellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinylpyrrolidone, pregelatinized starch, stearic acid, talc, titanium dioxide

Questions or comments?

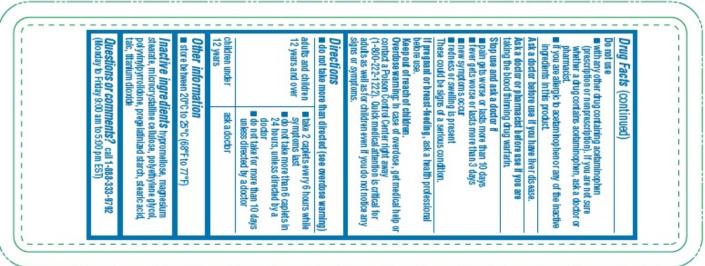
1-888-333-9792

PRINCIPAL DISPLAY PANEL

EXTRA STRANGTH PAIN RELIEVER

ACETAMINOPHEN 500 MG CAPLETS





EXTRA STRENGTH ACETAMINOPHEN

acetaminophen tablet, film coated

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ı	Product information			
	Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-0131
ı	Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients		
Ingredient Name	Strength	
HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)		
STARCH, CORN (UNII: O8232NY3SJ)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

Product Characteristics				
Color	white	Score	no score	
Shape	OVAL	Size	18mm	
Flavor		Imprint Code	S500	
Contains				

П	Packaging			
7	tem Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:70677- 0131-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/06/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/06/2021	

Labeler - Strategic Sourcing Services, LLC (116956644)

Revised: 12/2023 Strategic Sourcing Services, LLC