

EXTRA STRENGTH ACETAMINOPHEN- acetaminophen tablet
Health Pharma USA LLC

Acetaminophen Extra Strength 500 mg

Active Ingredient

(in each tablet)

Acetaminophen 500mg

Purpose

Pain reliever/fever reducer

Uses

- temporary relieves minor aches and pains due to
- the common cold
- headache
- backache
- toothache
- muscular aches
- premenstrual and menstrual cramps and
- 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 have ever had an allergic reaction to this product or any of its ingredients

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: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (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.

Do not exceed recommended dosage.

Directions

- do not use more than directed (**see overdose warning**)
- Adults and children 12 years of age and older:
- 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 more than 10 days unless directed by a doctor.
- Children under 12 years of age: Do not use this extra strength product. This will provide more than the recommended dose (overdose) and could cause serious health problems.

Other Information

- store at controlled room temperature 20-25°C (68-77°F).
- read all product information before using.
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Inactive Ingredients

Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Pregelatinized Starch, Polyethylene Glycol, Polyvinyl Pyrolidone, Stearic Acid, Talc, Titanium Dioxide

Questions or Comments

Call toll free 1-844-832-1138 Monday through Friday 9AM-5PM EST

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Health Pharma
Extra Strength Pain Reliever
Acetaminophen 500 mg
 Pain Reliever / Fever Reducer
 For Adults Aspirin Free
500 CAPLETS-500 mg Each

Drug Facts
Active ingredient (in each caplet) Acetaminophen 500mg Pain reliever, fever reducer
Purpose Pain reliever, fever reducer
Uses Temporarily relieves minor aches and pains due to: ■ headache ■ muscular aches ■ backache ■ minor pain of arthritis ■ the common cold ■ toothache ■ temporarily reduces fever ■ menstrual and menstrual cramps
Warnings Liver Warning: This product contains acetaminophen. The maximum daily dose of this product is 6 caplets (3000 mg) in 24 hours. Severe liver damage may occur if you take ■ more than 4000 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 rash/ hives ■ blisters ■ pain. If skin reaction occurs, stop use and seek medical help right away. Do not use ■ if you are taking other drugs containing acetaminophen (prescription or not prescription). 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 your doctor or pharmacist before use if you are taking the blood thinning drug warfarin more than 3 days ■ 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.
Keep out of reach of children. In preparation or breast-feeding, ask a health professional before use. If you experience symptoms of overdose, get medical help or contact a Poison Control Center (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 of age and over: ■ take 2 caplets every 6 hours while symptoms last. Do not take more than 6 caplets in 24 hours. ■ children 6 to 11 years of age: ■ take 1 caplet every 6 hours as directed by a doctor. ■ do not use for more than 10 days unless directed by a doctor. ■ children under 12 years of age: do not use this extra strength product. This will provide more than recommended dose (overdose) and could cause serious health problems.
Other information ■ store at controlled room temperature 20-25°C (68-77°F) ■ keep all product information before use ■ TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING
Inactive ingredients: May Contain: Pregelatinized starch, sodium starch glycolate, PVP-K30, stearic acid, hydroxy propyl methylcellulose, polyethylene glycol, talc, titanium dioxide
Questions or comments? Call toll free 1-844-832-1138 Mon - Fri 9AM - 5PM EST
 * This product is not manufactured or distributed by McKel Consumer Healthcare, owner of the registered trademark Extra Strength Tylenol®. Lot No.: 71679 Exp. Date: 6
 Mig / Dist by: Health Pharma, Rahway, NJ 07065, MADE IN THE USA, WWW.HEALTHPHARMA.COM

Extra Strength Pain Reliever 500mg Caplets

NDC 71679-107-05

Count: 500

EXTRA STRENGTH ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71679-107
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
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3S)	
POVIDONE (UNII: FZ989GH94E)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

TALC (UNII: 7SEV7J4R1U)

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	AP;500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71679-107-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	01/27/2022	

Labeler - Health Pharma USA LLC (080804485)

Establishment

Name	Address	ID/FEI	Business Operations
Health Pharma USA LLC		080804485	manufacture(71679-107)

Revised: 10/2023

Health Pharma USA LLC