

PAIN RELIEVER- acetaminophen tablet, film coated
HHH PHARMA USA LLC

Active ingredient (in each caplet)

Acetaminophen 500 mg

Purpose

Pain reliever/Fever reducer

Uses:

- temporarily relieves minor aches and pains due to:
- headache
- muscular aches
- backache
- minor pain from arthritis
- the common cold
- toothache
- temporarily reduces fever
- premenstrual 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 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: Taking more than 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.

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
- do not use for more than 10 days unless directed by a doctor
- children under 12 years of age: do not use

Other information

- store at 15° to 30°C (59° to 86°F)
- read all product information before using

Inactive ingredients

Pregelatinized Starch, Povidone, Stearic Acid powder, Microcrystalline Cellulose, Magnesium Stearate, Hypromellose 5 & 15, Polyethylene Glycol, Titanium Dioxide, Talc

Questions or comments?

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Compare to EXTRA STRENGTH
Tylenol® active ingredients*

Extra Strength

Pain Reliever

Acetaminophen 500 mg

Pain Reliever / Fever Reducer

For Adults

Aspirin Free

100 Caplets

NDC 83586-107-01

Drug Facts

Active Ingredient (in each caplet)

Acetaminophen 500mg 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
- premenstrual 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 or 3 or more alcoholic drinks everyday while using this product. **Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include: skin reddening, blisters, rash. If skin reaction occurs; stop use and seek medical help right away.

Do not use

- with any other drug 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.

DRUG FACTS CONTINUED on back of the label ►

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL
UNDER CAP IS BROKEN OR MISSING**

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Extra Strength Tylenol®.

PEEL HERE ►

Distributed by:
HHH Pharma USA LLC
Rahway, NJ 07065
www.hhhpharma.com

acetaminophen tablet, film coated

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83586-107
Route of Administration	ORAL		

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 365FW2JZ0W)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (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	CAPSULE	Size	17mm
Flavor		Imprint Code	S500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83586-107-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/12/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	08/12/2025	

Labeler - HHH PHARMA USA LLC (062788820)

Registrant - HHH PHARMA USA LLC (062788820)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals Ltd		863182240	manufacture(83586-107)

Establishment

Name	Address	ID/FEI	Business Operations
HHH PHARMA USA LLC		062788820	pack(83586-107)

