PAIN RELIEVER- acetaminophen tablet, film coated
Health Pharma USA LLC

Active ingredient (in each tablet)

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 tablets (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 mote than 6 tablets 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, Polyethylene Glycol, Titanium Dioxide, Talc

Questions or comments?

Call +1-844-832-1138 Mon - Fri 9 AM - 5 PM EST

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Debossed APAP 500	**Acetaminophen Tablets USP 500 mg** Each Film Coated Tablet Contains: Acetaminophen USP 500 mg
Batch No.: **Mfg. Date:** **Exp. Date:** **Repack Before Date:**	**Shipper No.:** **Quantity: 31,000 Tablets** **NDC No.: 71679-304-00**
WARNING: KEEP OUT OF THE REACH OF CHILDREN	
STORE AT CONTROLLED ROOM TEMPERATURE OF 59° F to 86° F (15°C to 30° C). PROTECT FROM LIGHT, MOISTURE AND FREEZING.	
THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE APPROVED, REPACKAGED IMMEDIATELY (9 MONTHS FROM MFG. DATE) AND LABELED IN STRICT CONFORMANCE WITH THE FD&C ACT AND REGULATIONS THERE UNDER.	
MANUFACTURED BY: **ELYSIUM PHARMACEUTICALS LTD.** MANUFACTURER CODE No.: G/25/1362 LABELER CODE # 14803	Manufactured For: **HEALTH PHARMA USA LLC** LABELER CODE: 71679 1600 Hart Street, Rahway, New Jersey (NJ) 07065, United States (USA)
CAUTION: "FOR MANUFACTURING, PROCESSING OR REPACKING"	

PAIN RELIEVER

acetaminophen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71679-304
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
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white ((white to off white))	**Score**	no score
Shape	ROUND	**Size**	12mm
Flavor		**Imprint Code**	APAP500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71679-304-00	31000 in 1 DRUM; Type 0: Not a Combination Product	10/09/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	10/09/2025	

Labeler - Health Pharma USA LLC (080804485)

Registrant - Health Pharma USA LLC (080804485)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals Ltd		863182240	manufacture(71679-304)

Establishment

Name	Address	ID/FEI	Business Operations
HHH Pharmaceuticals		144848997	pack(71679-304)