

ACETAMINOPHEN- acetaminophen tablet, film coated
Health Pharma USA LLC

Active ingredient (in each tablet)

Acetaminophen 325 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
- premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 10 tablets (3,250 mg) in 24 hours for adults or 5 tablets (1,625 mg) in 24 hours for children. Severe liver damage may occur if:

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adults has 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 the user has

liver disease

Ask a doctor or pharmacist before use if the user is

taking the blood thinning drug warfarin

Stop use and ask a doctor if:

- pain gets worse or lasts more than 10 days in adults
- pain gets worse or lasts more than 5 days in children under 12 years
- 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

- ***adults and children 12 years and over:***
- take 2 tablets every 4 to 6 hours while symptoms last
- do not take more than 10 tablets in 24 hours, unless directed by doctor
- do not use for more than 10 days unless directed by a doctor
- ***children 6 years to under 12 years:***
- take 1 tablet every 4 to 6 hours while symptoms last
- do not take more than 5 tablets in 24 hours
- do not use for more than 5 days unless directed by doctor

Other information

- store between 20°-25°C (68°-77°F)
- read all product information before using
- **TEMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

Inactive ingredients

Pregelatinized Starch, Polyvinyl Pyrrolidone, Microcrystalline Cellulose, Stearic acid powder, Magnesium Stearate, Hypromellose-5 & 15, Polyethylene Glycol-400, Talc, Titanium Dioxide.

Questions or comments?

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

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

<u>ACETAMINOPHEN TABLETS USP, 325 MG</u>			
Each Film coated tablet contains: Acetaminophen USP, 325 mg			
Batch No.	:		Mfg. Date
Shipper No.	:		Exp. Date
Quantity	:	47,000 Tablets	Repack Before Date
NDC No.	:	71679-305-00	
WARNING: KEEP OUT OF THE REACH OF CHILDREN			
Store At USP Controlled Room Temperature of 59 °F to 86 °F (15° C to 30° C). Protect from Light, Moisture and Freezing			 HANDLE WITH CARE “S99” Debossed
This is a Bulk Shipment Intended for Further Processing Only. Contents Should Be Approved, Repackaged Immediately (9 Month from MFG. Date) and labelled in strict conformance with the FD&C Act and Regulations There Under.			
Manufactured By:		Manufactured For:	
ELYSIUM PHARMACEUTICALS LIMITED At & Post – Dabhasa, Tal.: Padra, Dist.: Vadodara, Gujarat – 391440, INDIA Manufacturer Code No.: GUJ/DRUGS/G/25/2258 Labeller Code #14803		HHH PHARMA USA LLC LABELER CODE# 83586 1560 Hart Street, Rahway, New Jersey (NJ) 07065, United States (USA)	
CAUTION: “FOR MANUFACTURING, PROCESSING OR REPACKING”			
CAUTION: “REMOVE SILICA GEL BAG BEFORE USE”			
S-068-00			

ACETAMINOPHEN

acetaminophen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71679-305
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
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Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
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 (White to off white)	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	S99
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71679-305-00	47000 in 1 DRUM; Type 0: Not a Combination Product	09/23/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	09/23/2025	

Labeler - Health Pharma USA LLC (080804485)

Registrant - Health Pharma USA LLC (080804485)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals Ltd		863182240	manufacture(71679-305)

Establishment

Name	Address	ID/FEI	Business Operations
HHH PHARMA USA LLC		062788820	pack(71679-305)

