

ACETAMINOPHEN- acetaminophen tablet
Elysium Pharmaceuticals Ltd.

Acetaminophen Tablets

Acetaminophen USP 500mg

for further packing and labelling

keep out of reach of children

keep out of reach of children and for further packing

Hypromellose, Magnesium stearate, Microcrystalline Cellulose , Pregelatinized Starch,
Polyethylene Glycol, Povidone , Stearic Acid powder, Titanium Dioxide, Talc,

anti-inflammatory and for further packing

Anti Inflammatory

label

OUTER LABEL:

<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.	:	14803-013-00	
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
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.			“S99” Debossed
Manufactured By:		Manufactured For:	
ELYSIUM PHARMACEUTICALS LIMITED At & Post – <u>Dabhasa</u> , Tal.: <u>Padra</u> Dist.: Vadodara, Gujarat – 391440, INDIA Manufacturer Code No.: GUJ/DRUGS/G/25/2258 Labeler Code #14803		PIONEER LIFE SCIENCES, LLC 40C Cotters Lane, Suite F, East Brunswick, New Jersey (NJ) 08816, United States (USA)	
CAUTION : “FOR MANUFACTURING, PROCESSING OR REPACKING”			
CAUTION : “REMOVE SILICA GEL BAG BEFORE USE”			
S-036-01			

ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14803-013
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
N-VINYLPYRROLIDINONE (UNII: 76H9G81541)	

STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	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:14803-013-00	47000 in 1 BOX; Type 0: Not a Combination Product	03/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	03/07/2024	

Labeler - Elysium Pharmaceuticals Ltd. (915664486)

Registrant - Elysium Pharmaceuticals Ltd. (863182240)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals Ltd.		915664486	manufacture(14803-013) , analysis(14803-013)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals Limited		863182240	pack(14803-013) , manufacture(14803-013)

Revised: 1/2026

Elysium Pharmaceuticals Ltd.