

**ACETAMINOPHEN- acetaminophen tablet
Elysium Pharmaceuticals Ltd.**

Acetaminophen Tablets extra strength

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

“S500” DEBOSSED	Acetaminophen Tablets USP, 500 mg “S500” Each Film Coated Tablet Contains: Acetaminophen USP 500 mg	
Batch No. :	Shipper No. :	
Mfg. Date :	Quantity :	31,000 Tablets
Exp. Date :	NDC No. :	14803-281-00
Repack Before Date :		
<u>WARNING: KEEP OUT OF THE REACH OF CHILDREN</u>		
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. DT.) 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 :	
<u>CAUTION: “FOR FURTHER MANUFACTURING, PROCESSING OR REPACKING”</u>		

ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	ND ^C 14803-281
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, PREGELATINIZED CORN (UNII: 08232NY3SJ)	
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	CAPSULE	Size	17mm
Flavor		Imprint Code	S500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14803-281-01	31000 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)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals Ltd.		915664486	manufacture(14803-281) , analysis(14803-281)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals Limited		863182240	manufacture(14803-281) , pack(14803-281)

Revised: 11/2025

Elysium Pharmaceuticals Ltd.