

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” DEBOSSSED | <u>Acetaminophen Tablets USP, 500 mg “S500”</u> 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. : 14803-281-00 |
| 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. 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 : |
| CAUTION : “FOR FURTHER MANUFACTURING, PROCESSING OR REPACKING” | |

ACETAMINOPHEN

acetaminophen tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:14803-281 |
| 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 |
|--|----------|
| 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 | 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) |