ACETAMINOPHEN- acetaminophen tablet, film coated
Rising Pharma Holdings, Inc.

Compare to active ingredient in Tylenol® Extra Strength†

Extra Strength
Acetaminophen
500 mg

*** Pain Reliever**
*** Fever Reducer**
*** Contains No Aspirin**

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Drug Facts

Active Ingredient (in each caplet) ***Purpose***

Acetaminophen USP, 500 mg.....Pain Reliever/Fever Reducer

Uses

- temporarily relieves minor aches and pains due to:
- the common cold
- headache
- backache
- minor pain from arthritis
- toothache
- muscular aches
- premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen.

Severe liver damage may occur if you take

- more than 4,000 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: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt 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 and over	■ take 2 caplets every 6 hours while symptoms last ■ do not take more than 6 caplets in 24 hours, unless directed by a doctor ■ do not use for more than 10 days unless directed by a doctor
children under 12 years	ask a doctor

Other information

- SODIUM FREE
- store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)
- see end panel for lot number and expiration date.

Inactive ingredients

Hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

Questions or comments? Call **1-844-474-7464**

†This product is neither manufactured nor distributed by the owner of the registered trademark Tylenol® Extra Strength.

Distributed by:
Rising Pharma Holdings, Inc.

East Brunswick, NJ 08816

Made in India

Mfg. Lic. No.: G/25/2258

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

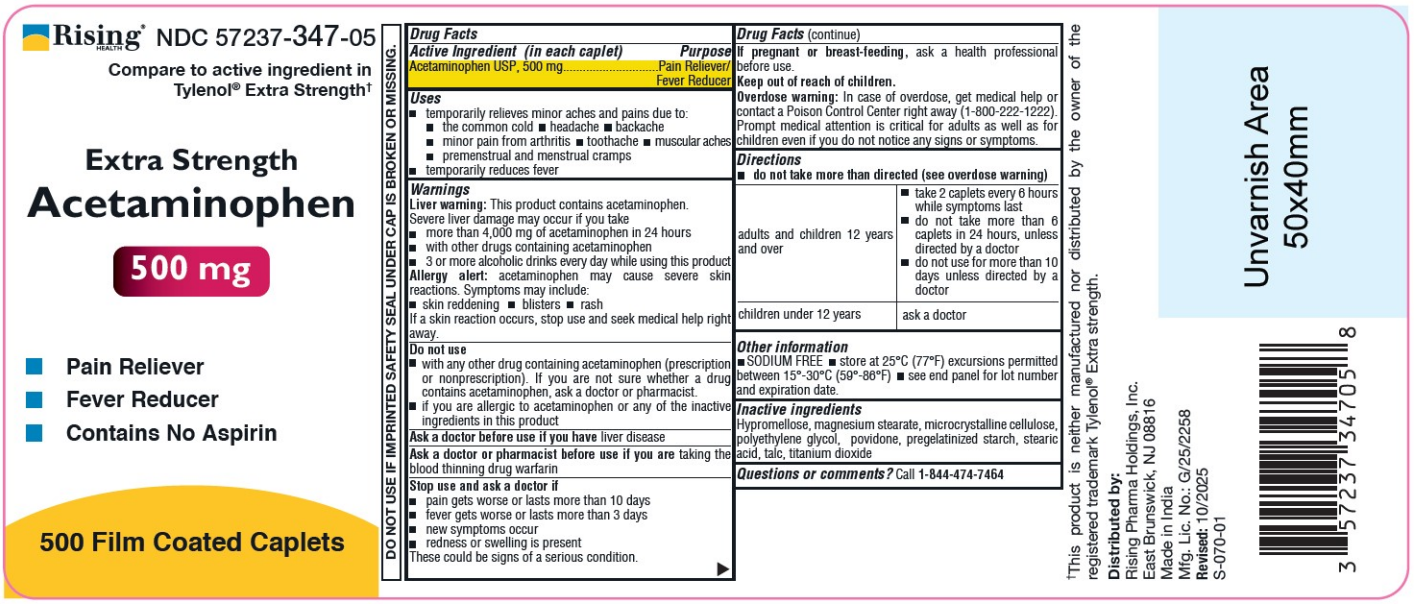
Extra Strength

Acetaminophen

500 mg

NDC 57237-347-05

500 Film Coated Caplets



ACETAMINOPHEN

acetaminophen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:57237-347
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, UNSPECIFIED (UNII: 3NXW29V3WO)	
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 (Off White)	**Score**	no score
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	S500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57237-347-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2025	
2	NDC:57237-347-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/04/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/09/2025	

Labeler - Rising Pharma Holdings, Inc. (116880195)

Registrant - Elysium Pharmaceuticals Ltd (863182240)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals Ltd		863182240	analysis(57237-347) , label(57237-347) , manufacture(57237-347) , pack(57237-347)

Revised: 10/2025 Rising Pharma Holdings, Inc.