

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**

100 Film Coated Caplets

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	<ul style="list-style-type: none">■ 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**

Distributed by:

Rising Pharma Holdings, Inc.

East Brunswick, NJ 08816

Made in India


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

Issued: 06/2025

S-064

†This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division, owner of the registered trademark Tylenol® Extra Strength.

100 Film Coated Caplets


Rising[®] NDC 57237-347-01

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 Tylenol[®] Extra Strength[†]

Extra Strength
Acetaminophen
500 mg

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- Fever Reducer
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OPEN FOR FULL LABELING

Drug Facts (continue)	
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Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin	
Stop use and ask a doctor if	<ul style="list-style-type: none"> ■ 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.
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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: 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 (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	

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)

