

**EXTRA STRENGTH ACETAMINOPHEN- acetaminophen capsule, gelatin coated
Pinnacle RX LLC**

251 mdr

Active ingredient (in each gelcap)

Acetaminophen 500 mg

Purpose

Pain Reliever/Fever Reducer

Uses

- temporarily relieves minor aches and pains
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen.

Severe liver damage may occur if you take:

- more than 8 gelcaps (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: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick 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**
- adults and children 12 years and over: Take 2 gelcaps every

6 hours, as needed; not more than 6 gelcaps in 24 hours.

Do not take for more than 10 days unless directed by a doctor.

- children under 12 years: ask a doctor

Other Information

- store at 20°C-25°C (68°F-77°F). avoid high humidity

Inactive Ingredients

Croscarmellose Sodium, D and C Red 33, FD and C Blue 1, FD and C Red 40, Gelatin, Hydroxypropyl Cellulose, Hypromellose, Iron Oxide, PEG, Povidone, Propylene Glycol, Shellac Glaze, Starch, Stearic Acid, Titanium Dioxide.

Questions or comments?

1-800-540-3765

Package label

MedRite
NDC 87438-0001-1

EXTRA STRENGTH
ACETAMINOPHEN
RAPID RELEASE
GELS

500mg
PAIN RELIEVER
FEVER REDUCER
100 GELCAPS

Compare to active ingredient in **TYLENOL®**
Extra Strength Rapid Release Gels*

TAMPER EVIDENT: Do not use if imprinted seal under cap is missing or broken.

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Questions or comments? 1-800-540-3765

* This product is not manufactured or distributed by the owner of the registered trademark **TYLENOL®**.
Dist by: Pinnacle Rx LLC
388 New Hempstead Rd.
Suite 6-65, New City, NY 10956
Questions or concerns?
Call (929) 269-6409

REV 251-0526
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EXTRA STRENGTH ACETAMINOPHEN

acetaminophen capsule, gelatin coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:87438-0001
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	red (red, gray and blue)	Score	no score
Shape	CAPSULE (Gelcap)	Size	19mm
Flavor		Imprint Code	L5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:87438-0001-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	05/01/2026	

Labeler - Pinnacle RX LLC (136361430)

