EXTRA STRENGTH PAIN RELIEVER- acetaminophen, aspirin and caffeine tablet, film coated
Proficient Rx LP

GC 226L (216)

Active ingredients (in each caplet)

ACETAMINOPHEN 250 MG

ASPIRIN 250 MG (nsaid-nonsteroidal anti-inflammatory drug)

CAFFEINE 65 MG

Purposes

PAIN RELIEVER - PAIN RELIEVER AID

USES

WARNINGS

Reye's Syndrome: Children and teenagers who have or are recovering from chicken pox or
flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could
be an early sign of Reye's syndrome, a rare but serious illness.
Allergy alert: Aspirin may cause a severe allergic reaction which may include:
• hives • facial swelling • asthma (wheezing) • shock
Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: • rash
• skin reddening • blisters If a skin reaction occurs, stop use and seek medical help right away.
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
Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach
bleeding. The chance is higher if you • have had stomach ulcers or bleeding problems
• take a blood thinning (anticoagulant) or steroid drug • take other drugs containing prescription
or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) • are age 60 or older
• have 3 or more alcoholic drinks every day while using this product
• take more or for a longer time than directed

Caffeine warning: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness,
irritability, sleeplessness, and, occasionally, rapid heartbeat.

Do not use

- if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer
- 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 have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if

- you have liver disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for diabetes, gout, or arthritis
- taking any other drug or are under a doctor’s care for any serious condition

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- ringing in the ears or loss of hearing occurs
- painful area is red or swollen
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- new symptoms occur These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of accidental overdose, get medical help or contact
a Poison Control Center (1-800-222-1222) right away. 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 use more than directed**
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 caplets every 6 hours; not more than 8 caplets in 24 hours
- children under 12: ask a doctor

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

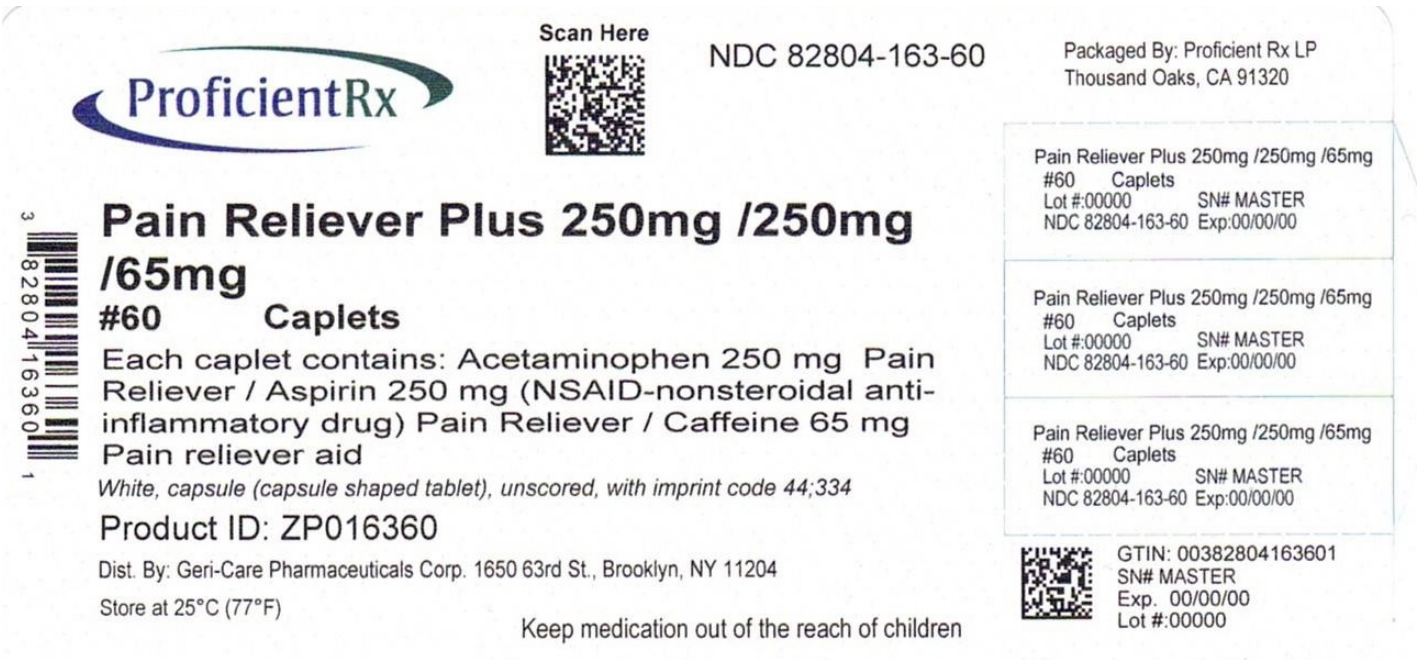
INACTIVE INGREDIENTS

corn starch, crospovidone, hypromellose,
microcrystalline cellulose, povidone, propylene glycol, sodium lauryl sulfate,
sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

1-800-540-3765

Package label



EXTRA STRENGTH PAIN RELIEVER

acetaminophen, aspirin and caffeine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:82804-163(NDC:57896-216)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	**Score**	no score
Shape	CAPSULE (CAPSULE SHAPED TABLET)	**Size**	17mm
Flavor		**Imprint Code**	44;334
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82804-163-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	02/01/2020	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(82804-163) , RELABEL(82804-163)

Revised: 11/2024 Proficient Rx LP