

**EXTRA STRENGTH PAIN RELIEVER- acetaminophen, aspirin and caffeine tablet,
film coated
PHARMACY VALUE ALLIANCE, LLC**

PV 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

- temporarily relieves minor aches and pains due to
- a cold
- toothache
- headache
- muscular aches
- arthritis
- premenstrual and menstrual cramps

WARNINGS

See carton for complete 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, croscopovidone, 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

ILKOCK
1 Ave
Wayne, NJ 07090

Premier Value

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

DISTRIBUTED BY:
PHARMACY VALUE ALLIANCE, LLC
407 EAST LANCASTER AVENUE
WAYNE, PA 19087

TAMPER EVIDENT: DO NOT USE IF THE IMPRINTED FOIL SEAL UNDER THE CAP IS BROKEN OR MISSING.

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SAVE CARTON FOR COMPLETE PRODUCT INFORMATION

Drug Facts
Active ingredients (in each caplet)
Acetaminophen 250 mg, Pain reliever
Aspirin 250 mg (NSAID), Pain reliever
Caffeine 65 mg, Pain reliever aid
*nonsteroidal anti-inflammatory drug

Uses
• temporarily relieves minor aches and pains due to:
• a cold • toothache • headache
• muscular aches • arthritis
• menstrual and menstrual cramps

Warnings
See carton for complete 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:
• shock • facial swelling
• hives • asthma (wheezing)
Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:
• skin redness • blisters • rash
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

COMPARE TO THE ACTIVE INGREDIENTS IN EXCEDIN®*

Premier Value

Extra Strength

Pain-Reliever

Acetaminophen 250mg
Aspirin 250mg (NSAID)
Caffeine 65mg

Caplets

100 Caplets





Drug Facts (continued)

- 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 take 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
 - do not take more than 8 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

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

Inactive ingredients contain starch, croscarellone, hypromellose, microcrystalline cellulose, polyvidone, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments? 1-800-546-3765

*This product is not manufactured or distributed by the owner of the registered trademark Excedin®.

REV 226-0120L

Drug Facts (continued)

- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) using this product • are age 60 or older
- 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 heartbeats.

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

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
 - have bloody or black stools • vomit blood
 - have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs
- redness or swelling is present



EXTRA STRENGTH PAIN RELIEVER
acetaminophen, aspirin and caffeine tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-762

Route of Administration	ORAL
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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)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPROVIDONE (UNII: 2S7830E561)	
POVIDONE (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:68016-762-00	1 in 1 CARTON	01/01/2020	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		

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

Labeler - PHARMACY VALUE ALLIANCE, LLC (101668460)

