

HEADACHE PAIN RELIEVER- acetaminophen, aspirin and caffeine tablet, film coated
PHARMACY VALUE ALLIANCE, LLC

PV 227I

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, 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



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.



Headache

Pain-Reliever

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

100 Caplets



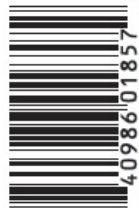
COMPARE TO THE ACTIVE INGREDIENTS IN EXCEDRIN®*

SAVE CARTON FOR COMPLETE PRODUCT INFORMATION

Drug Facts	Purpose
Active ingredients (in each caplet) Acetaminophen 250 mg..... Pain reliever Aspirin 250 mg (NSAID)..... Pain reliever Caffeine 65 mg..... Pain reliever *nonsteroidal anti-inflammatory drug	
Uses • temporarily relieves minor aches and pains due to: • a cold • toothache • 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: • shock • facial swelling • hives • asthma (wheezing) 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. 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	

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 corn starch, croscopolone, hypromellose, microcrystalline cellulose, povidone, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide
Questions or comments? 1-800-540-3765 *This product is not manufactured or distributed by the owner of the registered trademark Excedrin®.

Drug Facts (continued) • take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) • have 3 or more alcoholic drinks every day while 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 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 • 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



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REV 227-0220L

HEADACHE PAIN RELIEVER

acetaminophen, aspirin and caffeine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-761
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)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPVIDONE (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:68016-761-00	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)

Registrant - Geri-Care Pharmaceutical Corp (611196254)

Revised: 10/2023

PHARMACY VALUE ALLIANCE, LLC