

PHYSICIANS CARE EXTRA STRENGTH PAIN RELIEVER- acetaminophen, aspirin, caffeine tablet, film coated
Acme United

Physicians Care Extra Strength Pain Reliever

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 250 mg.

Aspirin (NSAID*) 250 mg

Caffeine 65 mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Pain reliever/fever reducer

Pain reliever aid

Uses

temporarily relieves minor aches and pains due to

■ headache ■ muscular aches ■ arthritis pain ■ a cold

■ toothache ■ premenstrual and menstrual cramps

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 (NSAIDs) 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:

■ 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 8 caplets in 24 hours, which is the maximum daily amount

■ 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:

- are age 60 or older
- 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)
- take more or for a longer time than directed
- have 3 or more alcoholic drinks every day while using this product

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 heart beat

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 ever have had an allergic reaction to any other pain relievers/ fever reducers

Ask a doctor before use if

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

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for gout, diabetes, or arthritis
- taking any other drug, or 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
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- ringing in the ears or loss of hearing occurs

- painful area is red or swollen

- any new symptoms appear

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health care 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 overdose, get medical help or contact a Poison Control Center

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 older) Take 2 caplets every 6 hours as needed; not more than 8 caplets in 24 hours

Children under 12 years: Ask a doctor

Other information

- read all product information before using

- store at room temperature 68°-77°F (20°-25°C)

- avoid excessive heat and humidity

- tamper evident sealed packets, do not use any opened or torn packets

Inactive ingredients

colloidal silicon dioxide, hypromellose, microcrystalline cellulose, polyvinyl pyrrolidone, polyethylene glycol, pregelatinized starch, starch 1500, stearic acid, talc

Questions or comments? 1-800-835-2263

90316

Physicians Care®

Extra Strength Pain Reliever

Acetaminophen, Aspirin (NSAID), and Caffeine

Pain Reliever / Pain Reliever Aid

Pull To Open

Coated Caplets

Tamper-Evident Packets of 2 Caplets

Do not use if packet is open or torn.

100 Caplets (50 Packets, 2 caplets each)



PHYSICIANS CARE EXTRA STRENGTH PAIN RELIEVER

acetaminophen, aspirin, caffeine tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0924-0131
Route of Administration	ORAL		

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

Inactive Ingredients	
Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
STEARIC ACID (UNII: 4ELV7Z 65AP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TALC (UNII: 7SEV7J4R1U)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	white (white to off white with specks)	Score	no score
Shape	CAPSULE (capsule shaped, biconvex)	Size	18mm
Flavor		Imprint Code	S53
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-0131-00	2 in 1 PACKET; Type 0: Not a Combination Product	06/07/2021	
2	NDC:0924-0131-01	50 in 1 BOX	06/07/2021	
2		2 in 1 PACKET; 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	06/07/2021	

Labeler - Acme United (001180207)

Registrant - UniFirst First Aid Corporation (832947092)