

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

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Physicians Care Extra Strength Pain Reliever

Drug Facts

Active ingredients (in each tablet)

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

For the temporary relief of minor aches and pains associated with

- headache
- muscular aches
- minor arthritis pain
- back pain
- common cold
- toothache
- menstrual cramps

Temporarily reduces fever.

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 or allergic 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:

- 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)
- 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 th

is 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.
- for pain for more than 10 days unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor
- if you ever have had an allergic reaction to any other pain relievers/ fever reducers
- right before or after heart surgery
- if you are taking prescription drugs for gout, diabetes, or arthritis

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 a history of stomach problems such as heartburn
- you have asthma

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking a prescription drug for gout, diabetes or arthritis

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- 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

- symptoms do not improve
- 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
- redness or swelling is present in the painful area
- any new symptoms appear

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 do not notice any signs or symptoms.

Directions

- **do not use more than directed**

Adults and children: (12 years and older)

Take 2 tablets with water every 6 hours as needed. Do not take more than 8 tablets in 24 hours.

Children under 12 years:

Do not give to children under 12 years of age.

Other information

- read all product information before using
- store at room temperature 59°-86°F (15°-30°C)
- avoid excessive heat and humidity
- do not use any opened or torn packets

Inactive ingredients

hypromellose, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, starch, stearic acid, titanium dioxide

Questions?

1-800-835-2263

Physicians Care XS Pain Reliever Label

90316

Physicians Care®

Extra Strength

Pain Reliever

Acetaminophen, Aspirin (NSAID) and Caffeine

Pain Reliever / Pain Reliever Aid

Pull To Open

This Package For Househlds Without Young Children.

Coated Tablets

Tamper-Evident Packets of 2 Tablets

Do not use if package is open or torn.

100 Tablets (50 Packets, 2 tablets each)

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 Caffeine 65 mg..... Pain reliever aid
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Caffeine warning: This product contains caffeine. 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.

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 ■ for pain for more than 10 days unless directed by a doctor
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 ■ if you ever have had an allergic reaction to any other pain relievers/fever reducers

Drug Facts (continued)
Ask doctor before use if
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 ■ you are taking a diuretic ■ you have asthma
 ■ you have a history of stomach problems such as heartburn

Ask a doctor or pharmacist before use if you are
 ■ taking the blood thinning drug warfarin
 ■ taking a prescription drug for gout, diabetes or arthritis

Stop use and ask a doctor if
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 ■ feel faint ■ vomit blood ■ have bloody or black stools
 ■ have stomach pain that does not get better
 ■ symptoms do not improve
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 ■ do not use more than directed
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Other information
 ■ read all product information before using
 ■ store at room temperature 59°-86°F (15°-30°C)
 ■ avoid excessive heat and humidity
 ■ do not use any opened or torn packets

Inactive Ingredients
 hypromellose, methylcellulose, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, starch, stearic acid, titanium dioxide

Questions? 1-800-835-2263

Contact Us 1-800-835-2263 www.FirstAidOnly.com

PHYSICIANS CARE EXTRA STRENGTH PAIN RELIEVER

acetaminophen, aspirin, caffeine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0924-0130
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

POVIDONE (UNII: FZ989GH94E)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	FR;9
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-0130-01	50 in 1 CARTON	09/27/2013	
1		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 not final	part343	09/27/2013	

Labeler - Acme United Corporation (001180207)

Establishment

Name	Address	ID/FEI	Business Operations
Prestige Packaging		170837962	repack(0924-0130) , relabel(0924-0130)

Revised: 10/2019

Acme United Corporation