

**ASPIRIN 81 MG- aspirin enteric coated tablets 81 mg tablet, delayed release
AACE Pharmaceuticals, Inc.**

corn starch, pregelatinized starch, povidone, microcrystalline cellulose, colloidal silicon dioxide, stearic acid, methacrylic acid and ethyl acrylate copolymer, talc, titanium dioxide, triethyl citrate, sodium bicarbonate, sodium lauryl sulfate, d&c yellow #10, hypromellose, triacetin

Aspirin 81 mg (NSAID*) *nonsteroidal anti-inflammatory drug

Ask a doctor before use if 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 you have not been drinking fluids you have lost a lot of fluid due to vomiting or diarrhea

Ask a doctor or pharmacist before use if you are - taking a prescription drug for diabetes, gout, or arthritis - taking any other drug - under a doctor's care for any serious condition

Aspirin Drug Facts

Do not use: if you are allergic to aspirin or any other pain reliver/fever reducer

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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.

Pain reliever

Stop use and ask a doctor if - an allergic reaction occurs. Seek medical help right away. - you are experiance 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 - pain gets worse or lasts more than 10 days - redness or swelling is present - new symptoms occur - ringing in the ears or a loss of hearing occurs. these could be signs of a serious condition.

Drink a full glass of water with each dose - adults and children 12 years and over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor - children under 12 years: consult a doctor

Reye's syndrome: Children and teenagers who have or are recoving 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 early sign of Reye's syndrome, a rare but serious illness.

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 steriod drug - take other drugs contiaining prescription or nonprescription NSAIDs (aspirin, ibuprofen,

naprozen, or others) - have 3 or more alcoholic drinks every day while using this product - take more or for longer time than directed

Allergy Alert: Aspirin may cause a severe allergic reaction which may include: - hives - facial swelling - shock - asthma (wheezing)

Pin Reliever

NDC 71406-128-12 AACE Pharmaceuticals - Adult Low Strength - Pain Reliever - Aspirin USP 81 mg (NSAID) Enteric Coated - 120 tablets - Compare to Active Ingredient in Aspirin Regimen BAYER®

Drug Facts

Active ingredient (in each tablet)
Aspirin 81 mg (NSAID)*, Pain reliever
*nonsteroidal anti-inflammatory drug

Purpose
Pain reliever

Uses
Temporarily relieves minor aches and pains
Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief. Ask your doctor about other uses for enteric-coated 81 mg Aspirin

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 ■ shock ■ asthma (wheezing)

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Do not use if you are allergic to aspirin or any other pain reliever/fever reducer

Drug Facts continued on back of label

UNVARNISHED AREA

LOT #:
EXP. DATE:

PEEL HERE FOR MORE DRUG FACTS

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Drug Facts (continued)

Ask a doctor before use if
 ■ 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
 ■ you have not been drinking fluids
 ■ you have lost a lot of fluid due to vomiting or diarrhea

Ask a doctor or pharmacist before use if you are
 ■ taking a prescription drug for diabetes, gout, or arthritis ■ taking any other drug
 ■ 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 ■ pain gets worse or lasts more than 10 days ■ redness or swelling is present
 ■ new symptoms occur ■ ringing in the ears or a loss of hearing occurs. These could be signs of a serious condition.

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Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions
 ■ drink a full glass of water with each dose
 ■ adults and children 12 years and over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor
 ■ children under 12 years: consult a doctor

Other information
 ■ store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)
 ■ use by expiration date on package

Inactive ingredients colloidal silicon dioxide, corn starch, D & C yellow #10, hypromellose, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polydioxane, pregelatinized starch, sodium bicarbonate, sodium lauryl sulfate, stearic acid, talc, titanium dioxide, triacetin, triethyl citrate.

STOP PEELING

NDC 71406-128-10 AACE Pharmaceuticals - Adult Low Strength - Pain Reliever - Aspirin USP 81 mg (NSAID) Enteric Coated - 1000 tablets - Compare to Active Ingredient in Aspirin Regimen BAYER®

Compare to active ingredient in Aspirin Regimen BAYER

AACE
Pharmaceuticals

NDC 71406-128-10

Adult Low Strength
Pain Reliever

Aspirin USP

Enteric Coated
81mg NSAID

THIS PACKAGE FOR HOUSEHOLDS
WITHOUT YOUNG CHILDREN

1000 Tablets

Drug Facts

Active ingredient (in each tablet)
Aspirin 81 mg (NSAID)¹.....Pain reliever
*nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains
- Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief.
- ask your doctor about other uses for enteric-coated 81 mg Aspirin

Warnings

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- hives
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- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Do not use if you are allergic to aspirin or any other pain reliever/fever reducer

Ask a doctor before use if

- stomach bleeding warning applies to you

Drug Facts continued on back of label

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING.

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Distributed by:
AACE Pharmaceuticals, Inc.,
Fairfield, NJ 07004
aacpharma.com

Rev. 01

LOT #: _____
EXP. DATE: _____

UNVARNISHED AREA

STOP PELLING

Drug Facts (continued)

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ASPIRIN 81 MG			
aspirin enteric coated tablets 81 mg tablet, delayed release			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71406-128
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ASPIRIN (UNII: R16C05Y76E) (ASPIRIN - UNII:R16C05Y76E)	ASPIRIN	81 mg
Inactive Ingredients			
	Ingredient Name		Strength
	TRIACETIN (UNII: XHX3C3X673)		

STEARIC ACID (UNII: 4ELV7Z65AP)
POVIDONE (UNII: FZ989GH94E)
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)
SODIUM LAURYL SULFATE (UNII: 368GB5141J)
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)
STARCH, CORN (UNII: O8232NY3SJ)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:2) (UNII: XRK36F13ZZ)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
SODIUM BICARBONATE (UNII: 8MDF5V39QO)
TALC (UNII: 7SEV7J4R1U)
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)

Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	S17
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71406-128-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2021	
2	NDC:71406-128-12	120 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	05/03/2021	

Labeler - AACE Pharmaceuticals, Inc. (080630748)

Revised: 12/2023

AACE Pharmaceuticals, Inc.