

ASPIRIN 81MG- aspirin enteric coated tablets 81mg tablet
VITANE PHARMACEUTICALS, INC

ACTIVE INGREDIENT

Aspirin 81 mg (NSAID*)

*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.

INACTIVE INGREDIENT

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.

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)

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

DO NOT USE SECTION

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 loss of hearing occurs
- these could be signs of a serious condition.

ASK DOCTOR/PHARMACIST SECTION

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for gout, diabetes, or arthritis
- taking any other medication
- under a doctor's care for any serious condition

STOP USE SECTION

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 loss of hearing occurs

these could be signs of a serious condition.

PREGNANCY OR BREAST FEEDING SECTION

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.

ASK A DOCTOR BEFORE USE

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

KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

STORAGE

- store at 25°C (77°F); excursions permitted between 15°and 30°C (59°and 86°F)
- -use by expiration date on package.

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

PRINCIPAL DISPLAY PANEL

NDC 60577-807-01

Vitane's

Aspirin 81mg

Pain Reliever -

Aspirin USP 81 mg (NSAID) Enteric Coated

60 tablets



Drug Facts

Active ingredient (in each tablet) Purpose

Aspirin 81 mg (NSAID).....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:

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 behaviour 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).

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.
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
- 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

MADE IN USA Drug Facts continued on the back of label

Virane Pharmaceuticals is not affiliated with the owner of the trademark BAYER®

MariZoumby,
Aspirin®/Enteric-coated tablets, Inc.
Manufactured For:
Virane Pharmaceuticals, Inc.
125 Webb Avenue, Campton,
New York, 10828-USA
www.virane-pharm.com
FACIS ELES08R2



LOT:
MFG:
EXP:

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are taking a prescription drug for: ■ gout ■ diabetes ■ arthritis

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 loss of hearing occurs

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 overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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°C and 30°C (59°F and 86°F)

Use by expiration date on package.

Inactive Ingredients: Corn Starch, BSC Yellow 40, 10, Hypromellose, Methacrylic Acid and Ethyl Acrylate Copolymer, Microcrystalline Cellulose, Polyvinylpyrrolidone, Polyethylene Glycol, Polysorbate 80, Sodium Bicarbonate, Sodium Lauryl Sulfate, Stearic Acid, Talc, Titanium Dioxide, Triacetin, Triethyl Citrate.

Questions or comments?

Call 1-845-267-6700 Monday through Friday, 8 am to 5 pm EST or www.viranepharma.com

Talk to your doctor before you begin an aspirin regimen.

WARNING: DO NOT USE THIS PRODUCT IF THE PRINTED POLYMER OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING.



ASPIRIN 81MG

aspirin enteric coated tablets 81mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60577-807
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

Inactive Ingredients				
Ingredient Name			Strength	
STARCH, CORN (UNII: O8232NY3SJ)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TALC (UNII: 7SEV7J4R1U)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)				
TRIACETIN (UNII: XHX3C3X673)				
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
POVIDONE (UNII: FZ989GH94E)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
Product Characteristics				
Color	yellow	Score	no score	
Shape	ROUND	Size	5mm	
Flavor		Imprint Code	S;17	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60577-807-01	1 in 1 CARTON	10/15/2025	
1		60 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		10/15/2025	

Labeler - VITANE PHARMACEUTICALS, INC (029029638)

Establishment			
Name	Address	ID/FEI	Business Operations
Aarkish Pharmaceuticals, NJ Inc		117729250	manufacture(60577-807)