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

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#### **ACTIVE INGREDIENT**

Aspirin 81 mg (NSAID\*)

\*nonsteroidal anti-inflamatory 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 celulose, 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
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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):..... Proneteroidal anti-inflammatory drug

Uses:

atompararily releves minor address and pains.

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CODE LOT : MFG: EXP :

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#### Directions:

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adults and children 12 Years and over, take 4 to 8 tablets
every 4 hours not to exceed 48 tablets in 24 hours unless
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in 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 36°F) • Use by expiration date on package.

Inactive Ingredients: Com Stardt, DSC Yellow Vo. 10, Hypromellose, Methacylic Add and Bhyl Acyldee Copolymer, Microopstaline Cebiblose, Poddone, Pregebilized Sack Siloon Blooke, Soldiem Beachmade, Soldiem Lauryl Suifate, Steatic Add, Talq. Thankim Dixxide, Triboetin, Trietyl Chrise.

Questions or comments? Call 1-845-267-6700 Wonday through Friday, 8 am to 5 pm EST or www.vitanephama.com

'Talk to your doctor before you begin an aspirin regimen.

TAMPER PAGENT: DONOTUSE THIS PRODUCT IF THE MPRINTED POLISEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROXEN 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				

P	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 Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	10/15/2025	

## Labeler - VITANE PHARMACEUTICALS, INC (029029638)

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