

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

ACTIVE INGREDIENT

Aspirin 81 mg (NSAID*)

*nonsteroidal anti-inflammatory drug

PURPOSE

Pain reliever

USES

- Temporarily relieves minor aches and pains
- For use as directed by a doctor for the prevention of recurrent heart attack or stroke

Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief.

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

Allergy Alert:

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

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 non-prescription NSAIDs(aspirin,

ibuprofen, naproxen, 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

Do not use if:

You are allergic to aspirin or any other pain reliever/fever reducer.

ASK A DOCTOR/PHARMACIST

Ask a doctor or pharmacist before use if you are taking a prescription drug for

- gout
- diabetes
- arthritis

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
 - vomit blood
 - have bloody or black stools
 - 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.

PREGNANCY OR BREAST FEEDING SECTION

If pregnant or breast-feeding, ask a health professional.

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 SECTION

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

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

STORAGE

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

INACTIVE INGREDIENTS

Microcrystalline Cellulose, Talc, Croscarmellose Sodium, Stearic Acid, Colloidal Silicon Dioxide, Titanium Dioxide, Triethyl Citrate, Methacrylic Acid and Ethyl Acrylate Copolymer, D&C Yellow #10, FD&C Yellow #6

ASK A DOCTOR BEFORE USE

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

PRINCIPAL DISPLAY PANEL

NDC 60577-808-01

Vitane's

Aspirin 81mg

Pain Reliever

Aspirin 81 mg (NSAID) Enteric Coated

60 tablets

Vitane's
NDC 06577-088-01

ASPIRIN
81 mg

Adult low dose Aspirin 81mg
Pain reliever (NSAID)
Safety seal Aspirin regimen
60 Tablets
Etiopiric Content
DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING
THIS SEAL HAS A VOID LINE WHICH PROVIDES PROTECTION FROM FALSIFICATION
Check for life




Drug Facts

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

Uses: temporarily relieves: muscle pain
menstrual pain minor pain of arthritis
Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief.

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 asthma (wheezing)
shock **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 (CONTINUED ON BACK OF LABEL)

Manufactured by
Irtan Health Inc.,
Manufactured For:
Vitane Pharmaceuticals, Inc.
125 Wells Avenue, Congers
New York, 10920-USA
www.vitanepharm.com

**QR
CODE**

LOT:
MPG:
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 vomit blood have bloody or black stools 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.

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 Year 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.

Other Ingredients: Microcrystalline Cellulose, Talc, Croscarmellose Sodium, Stearic Acid, Colloidal Silicon Dioxide, Titanium Dioxide, Triethyl Citrate, Methacrylic Acid and Ethyl Acrylate Copolymer, D&C Yellow #10, FD&C Yellow #6.

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

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

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER GAP IS BROKEN OR MISSING.



ASPIRIN 81MG

aspirin enteric coated tablets 81mg tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60577-808
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
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)				
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)				
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
TALC (UNII: 7SEV7J4R1U)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				

Product Characteristics			
Color	yellow	Score	no score
Shape	ROUND	Size	4mm
Flavor		Imprint Code	l1
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60577-808-01	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
InvaHealth Inc		116840615	manufacture(60577-808)