

PAIN RELIEVER- aspirin 81 mg tablet, delayed release
Health Pharma USA, LLC

Active ingredient (in each caplet)

Aspirin 81mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain Reliever

Uses:

- temporary relief of minor aches and pains or as recommended by your doctor.
Because of its delayed release 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: Aspirin may cause a severe allergic reaction which may include:

- hives
- shock
- facial swelling
- 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

- you have asthma
- 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

Ask a doctor or pharmacist before use if you are

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

Stop use and ask a doctor if

- 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
- an allergic reaction occurs.

Seek medical help right away.

- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- redness or swelling present in the painful area
- new symptoms occur

These could be sign of a serious condition

If pregnant or breast-feeding,

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. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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 while symptoms last
 - not to take more than 48 tablets in 24 hours unless directed by a doctor
- children under 12 years: ask a doctor

Other information

- store at room temperature 15-30°C (59-86°F)
- read all product information before using

Inactive ingredients:

Acrycoat, Colloidal Silicon Dioxide, Croscarmellose Sodium, D&C Yellow# 10, Yellow Oxide of Iron, Lactose, Microcrystalline Cellulose, Polysorbate 80, Sodium Hydroxide, Talc, Titanium Dioxide, Triethyl Citrate.

Questions or comments?

Call toll free 1-844-832-1138

Monday through Friday 9AM – 4PM EST

PRINCIPAL DISPLAY PANEL

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71679-104
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
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
LACTOSE (UNII: J2B2A4N98G)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
TALC (UNII: 7SEV7J4R1U)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	

Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	A1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71679-104-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2027	
2	NDC:71679-104-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2027	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	06/13/2025	

Labeler - Health Pharma USA, LLC (080804485)

Registrant - Health Pharma USA, LLC (080804485)

Establishment

Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LIMITED		915664486	manufacture(71679-104)

Establishment

Name	Address	ID/FEI	Business Operations
HHH PHARMA USA LLC		062788820	pack(71679-104)

Revised: 6/2025

Health Pharma USA, LLC