

ASPIRIN 81MG ENTERIC COATED- aspirin tablet, delayed release
HHH 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 +1 848-235-5293 Monday through Friday 9AM-4PM EST

PRINCIPAL DISPLAY PANEL-500's Count

Drug Facts (Continued)	
Ask a doctor before use if <ul style="list-style-type: none">■ 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 <ul style="list-style-type: none">■ 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 <ul style="list-style-type: none">■ 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. <p>These could be signs of a serious condition.</p>	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 <ul style="list-style-type: none">■ drink a full glass of water with each dose■ adults and children 12 years and over:<ul style="list-style-type: none">■ take 4 to 8 tablets every 4 hours while symptoms last■ do not take more than 48 tablets in 24 hours■ unless directed by a doctor■ children under 12 years: ask a doctor	Other information <ul style="list-style-type: none">■ store at room temperature 15-30°C (59-86°F)■ read all product information before using
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NDC 83586-104-05


Compare to Bayer® Low Dose Aspirin active ingredients*

Adult Low Dose

ASPIRIN


Aspirin 81 mg
Pain Reliever (NSAID)
Safety Coated
Aspirin Regimen

500 Tablets

Drug Facts
Purpose Active ingredient (in each caplet) Aspirin 81 mg (NSAID)* Pain reliever * nonsteroidal anti-inflammatory drug
Uses: <ul style="list-style-type: none">■ temporarily 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 headache or symptoms needing immediate relief.
Warnings <p>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.</p> <p>Allergy alert: Aspirin may cause a severe allergic reaction, which may include: ■ hives ■ shock ■ facial swelling ■ asthma (wheezing)</p> <p>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</p> <p>Do not use ■ if you are allergic to aspirin, or any other pain reliever/fever reducer</p>
DRUG FACTS CONTINUED on back of the label ▶
TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING
<small>*This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Bayer® Low Dose Aspirin. Distributed by: HHH Pharma USA LLC, Rahway, NJ 07065 www.hhhpharma.com</small>
 <p>3 83586 10405 9</p> <p>PEEL HERE</p>

PRINCIPAL DISPLAY PANEL-1000's Count

NDC 83586-104-10



Compare to Bayer® Low Dose Aspirin active ingredients*

Adult Low Dose

ASPIRIN

Aspirin 81 mg
Pain Reliever (NSAID)
Safety Coated
Aspirin Regimen

1000 Tablets

Drug Facts

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

Purpose
Pain reliever


Uses
■ temporarily 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 headache or symptoms needing immediate relief.

Warnings
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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, 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 ■ do not take more than 48 tablets in 24 hours unless directed by a doctor ■ **children under 12 years:** ask a doctor
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TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING
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 +1 848-255-5293 Monday through Friday 9AM - 5PM EST
*This product is not manufactured or distributed by Bayer Healthcare LLC, owner of the registered trademark Bayer® Low Dose Aspirin.

Distributed by:
HHH Pharma USA LLC
Rahway, NJ 07065
www.hhhpharma.com


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ASPIRIN 81MG ENTERIC COATED

aspirin tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83586-104
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name		Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)		81 mg

Inactive Ingredients	
Ingredient Name	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
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)	

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:83586-104-05	1000 in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2025	
2	NDC:83586-104-10	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2025	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013		07/23/2025	

Labeler - HHH PHARMA USA LLC (062788820)

Registrant - HHH PHARMA USA LLC (062788820)

Establishment			
Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LIMITED		863182240	manufacture(83586-104)

Establishment			
Name	Address	ID/FEI	Business Operations
HHH PHARMA USA LLC		062788820	pack(83586-104)