

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

Pain Reliever - Aspirin Delayed Release Tablets, 81 mg

Drug Facts

Active Ingredients (in each tablet)

Aspirin 81 mg (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, 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.

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

Inactive ingredients

Starch, Povidone, Microcrystalline cellulose, Crosscarmellose Sodium, Methacrylic acid copolymer and ethyl acrylate co-polymer, Triethyl citrate, Talc, Fumed Silica, Titanium Dioxide, D&C Yellow #10, FD&C Yellow#6

Questions or comments?

Call toll free 1-844-832-1138

Monday through Friday 9AM - 5PM EST

PRINCIPAL DISPLAY PANEL

See New Warnings Information

Compare to Bayer[®] Low Dose Aspirin active ingredients*

*This product is not manufactured or distributed by Bayer HealthCare LLC., owner of the registered trademark Bayer[®] Low Dose Aspirin.

Aspirin Delayed Release Tablets, 81 mg

500 ENTERIC Coated Tablets

SEE NEW WARNINGS INFORMATION

- safety coated aspirin regimen
- delayed release
- safe pain relief

Pain Reliever (NSAID)

Aspirin

Adult Low Dose

Compare to Bayer® Low Dose Aspirin active ingredients*

Health Pharma

NDC 71679-104-05

Drug Facts

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

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

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

DRUG FACTS CONTINUED on back of the label ▶

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

*This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Bayer® Low Dose Aspirin.

Mfg / Dist by:
Health Pharma
Rahway, NJ 07065
www.health-pharma.us



Lot No.:
Exp. Date:



PEEL HERE ▶

Drug Facts (Continued)

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 signs of a serious condition.

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Other information

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

Inactive ingredients: May Contain:

Starch, Povidone, Microcrystalline Cellulose, Croscarmellose Sodium, Stearic Acid, Colloidal Silicon Dioxide, Methacrylic acid and ethyl acrylate co-polymer, Triethyl Citrate, Talc, Fumed Silica, Titanium Dioxide, D&C Yellow #10, FD&C Yellow #6

Questions or comments? Call toll free 1-844-832-1138 Monday through Friday 9AM - 4PM EST

PAIN RELIEVER

aspirin 81 mg tablet, delayed release

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:71679-104

Route of Administration	ORAL
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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)	
POVIDONE (UNII: FZ989GH94E)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
TALC (UNII: 7SEV7J4R1U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

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	01/21/2022	
2	NDC:71679-104-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	01/21/2022	

Labeler - Health Pharma USA LLC (080804485)

Establishment

Name	Address	ID/FEI	Business Operations
Health Pharma USA LLC		080804485	manufacture(71679-104)

Revised: 10/2023

Health Pharma USA LLC