

**PAIN RELIEVER- aspirin 81 mg tablet, delayed release
HealthLife Of USA**

Pain Reliever - Aspirin Delayed Release Tablets, 81 mg

Drug Facts

Active Ingredients (in each caplet)

Purpose

Aspirin 81 mg (NSAID)* Pain reliever

*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 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; do not 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

May Contains:

Starch, Povidone, Microcrystalline cellulose, Crosscarmellose Sodium, Stearic Acid, Colloidal Silicon Dioxide, 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 1-844-832-1138

9AM - 5PM EST Monday - Friday

PRINCIPAL DISPLAY PANEL

See New Warnings Information & Directions

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

HealthLife® NDC 69517-104-10

Compare to Bayer® Low Dose Aspirin active ingredients*

Adult Low Dose

Aspirin

Aspirin 81 mg Pain Reliever (NSAID)

Safety Coated Aspirin Regimen

SEE NEW WARNINGS INFORMATION

1000 TABLETS

Drug Facts

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* nonsteroidal anti-inflammatory drug

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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

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■ you experience any of the following signs of stomach bleeding: ■ feel faint ■ you have bloody or black stools ■ vomit blood ■ have stomach pain that does not get better ■ an allergic reaction occurs. Seek medical help right away.
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Other information
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Inactive ingredients: Corn Starch, Propylparaben, Povidone, Microcrystalline Cellulose, Stearic Acid, Colloidal Silicon Dioxide, Methacrylic acid and ethyl acrylate copolymer, Triethyl Citrate, Talc, Titanium Dioxide, Silica, Sodium bicarbonate, Sodium lauryl sulfate, D&C Yellow #10, Hydroxyethylcellulose, Triacetin

Questions or comments? Call toll free 1-844-832-1138 Monday through Friday 9AM - 5PM EST

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Lot No.: _____ Exp. Date: _____

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HealthLife® NDC 69517-104-05

Compare to Bayer® Low Dose Aspirin active ingredients*

Adult Low Dose

Aspirin

Aspirin 81 mg Pain Reliever (NSAID)

Safety Coated Aspirin Regimen

500 TABLETS

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Drug Facts (Continued)

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PAIN RELIEVER			
aspirin 81 mg tablet, delayed release			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69517-104

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
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
TALC (UNII: 7SEV7J4R1U)	
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	A
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69517-104-25	25 in 1 BOX	06/05/2017	06/05/2017
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:69517-104-50	50 in 1 BOX	06/05/2017	06/05/2017
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:69517-104-02	2 in 1 POUCH	06/05/2017	06/05/2017
3		2 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:69517-104-01	1000 in 1 BOTTLE	06/05/2017	
4	NDC:69517-104-65	365 in 1 BOTTLE		
4	NDC:69517-104-30	30 in 1 BOTTLE		

4		1 in 1 CARTON; Type 0: Not a Combination Product		
5	NDC:69517-104-60	1 in 1 CARTON	06/05/2017	
5		60 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:69517-104-03	300 in 1 BOTTLE; Type 0: Not a Combination Product	11/29/2023	
7	NDC:69517-104-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/29/2023	
8	NDC:69517-104-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/29/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	02/09/2016	

Labeler - HealthLife Of USA (079656178)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceutical Ltd.		915664486	manufacture(69517-104)

Establishment

Name	Address	ID/FEI	Business Operations
Health Pharma USA LLC		080804485	manufacture(69517-104)

Revised: 11/2023

HealthLife Of USA