

SAFETY COATED ASPIRIN 81 MG LOW DOSE- aspirin 81mg tablet, delayed release

Ulai Health LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient (in each tablet)

Aspirin 81mg (NSAID) †

†nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

- for the 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 headache or other symptoms needing immediate relief.**
- ask your doctor about other uses for this product

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
- 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
- if you have ever had an allergic reaction to this product or any of its ingredients

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

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
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- any 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 right away (1-800-222-1222).

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	ask a doctor

Other information

- store at 20-25 °C (68-77 °F)
- avoid excess heat and moisture

Inactive ingredients

croscarmellose sodium, D&C yellow # 10, FD&C yellow #6, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, silicon dioxide, sodium bicarbonate, sodium lauryl sulfate, starch, stearic acid, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?

(866) 562-2756 (Mon- Fri 8 AM to 4 PM EST)

PHARBEST

NDC 73057-356-11

Manufactured in the USA

Aspirin Regimen

***Compare to the active ingredient in Bayer® Low Dose**

Safety Coated


Aspirin 81 mg

Low Dose

81 mg PAIN RELIEVER (NSAID)

1000 ENTERIC COATED TABLETS

Talk to your doctor or other healthcare provider before using this product for your heart.

PHARBEST  **Manufactured in the USA**
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Aspirin Regimen *Compare to the active ingredient in Bayer® Low Dose

Safety Coated

Aspirin 81 mg
Low Dose

81mg PAIN RELIEVER (NSAID)

1000 ENTERIC COATED TABLETS

Talk to your doctor or other healthcare provider before using this product for your heart.

THIS PACKAGE FOR HOUSEHOLD WITHOUT YOUNG CHILDREN

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

Drug Facts

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

Uses
■ for the temporary relief of minor aches and pains or as recommended by your doctor.
■ to help reduce the risk of heart disease and stroke in people at high risk for heart disease or other symptoms leading to immediate heart attack. ■ ask your doctor about other uses for this product.

Warnings
■ **Caution:** 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 ■ 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 ulcers or bleeding in your stomach or intestines ■ take other drugs containing aspirin or nonsteroidal anti-inflammatory drugs (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 ■ if you have ever had an allergic reaction to this product or any of its ingredients
■ **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 ■ you are taking a prescription drug for ■ gout ■ diabetes ■ arthritis ■ blood thinners ■ or ■ any other medical condition

Stop use and ask a doctor if ■ allergic reaction occurs. Seek medical help right away if you experience any of the following: ■ severe stomach pain that does not get better ■ pain gets worse or lasts more than 10 days ■ fewer gets worse or lasts more than 3 days ■ redness or swelling is present ■ new symptoms occur ■ ringing in the ears or a loss of hearing occurs

If pregnant or breast-feeding, ask a health professional before use. It is especially important to use this product during pregnancy or while breastfeeding 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 right away (1-800-222-1222).

Directions
■ drink a full glass of water with each dose
■ adults and children 12 years and over ■ take 4 to 6 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor
■ children under 12 years ■ ask a doctor

Other information ■ store at 20-25°C (68-77°F) ■ avoid excess heat and moisture

Inactive ingredients: croscarmellose sodium, D&C yellow #10, FD&C yellow #6, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, silicon dioxide, sodium bicarbonate, sodium lauryl sulfate, starch, stearic acid, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments? (866) 562-2756 (Mon-Fri 8 AM to 4 PM EST)

This product is not recommended for children under 12 years of age without the supervision of a doctor.
Bayer® Low Dose.

Distributed by:
ULAI HEALTH LLC.
Alexandria, VA 22312

Org. 06/19
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SAFETY COATED ASPIRIN 81 MG LOW DOSE

aspirin 81mg tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73057-356
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	yellow (YELLOW COLOR)	Score	no score
Shape	ROUND (ROUND TABLET)	Size	8mm
Flavor		Imprint Code	PH;023
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73057-356-11	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/28/2019	
2	NDC:73057-356-09	120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/28/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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Labeler - Ulai Health LLC (081181535)

Revised: 1/2022

Ulai Health LLC