

## **ASPIRIN REGULAR STRENGTH- aspirin 325mg tablet**

### **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 325mg (NSAID) †

†nonsteroidal anti-inflammatory drug

#### **Purpose**

Pain reliever/fever reducer

#### **Uses**

- temporarily relieves minor aches and pains due to:
- headache
- muscle pain
- toothache
- menstrual pain
- colds
- minor pains of arthritis
- temporarily reduces fever

#### **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
- ringing in the ears or loss of hearing occurs
- new symptoms occur

### **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 take 1 to 2 tablets every 4 hours or 3 tablets every 6 hours,

years and over not to exceed 12 tablets in 24 hours  
 children under 12 years ask a doctor

### Other information

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

### Inactive ingredient

corn starch

### Questions or comments?

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

**PHARBEST**

**NDC 73057-365-11**

**Manufactured in the USA**

**\*Compare to the active ingredient in Genuine Bayer® Aspirin**

**Aspirin**

**Regular Strength**

**Pain Reliever/Fever Reducer (NSAID)**

**1000 TABLETS**

**Aspirin, 325 mg each**

**PHARBEST** **Manufactured in the USA**  
 NDC 73057-365-11

*Compare to the active ingredient in Genuine Bayer® Aspirin*

# Aspirin

**Regular Strength**

**Pain Reliever/Fever Reducer (NSAID)**

**1000 TABLETS**  
 Aspirin, 325 mg each

**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)** *Proprietary*  
 Aspirin 325 mg (NSAID)..... Pain reliever/fever reducer  
 Nonsteroidal anti-inflammatory drug

**Uses**

- temporarily relieves minor aches and pains due to: ■ headache ■ muscle pain
- toothache ■ menstrual pain ■ colds ■ minor pain of arthritis ■ temporarily reduces fever

**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 if 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 (like ibuprofen, naproxen, or celecoxib) ■ have 3 or more alcoholic drinks a day while using this product ■ use more than one NSAID in the last 30 days ■ have a history of ulcers or bleeding from the stomach ■ are taking aspirin or aspirin along with other drugs ■ are taking aspirin after liver failure ■ you have a history of 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 ■ 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 go away ■ have black or tarry stools ■ have dark, bloody, or tarry stools ■ have a rash ■ have a sore on the tongue ■ have a sore on the lips ■ have a sore on the nose ■ have a sore on the throat ■ have a sore on the skin ■ have a sore on the eyes ■ have a sore on the ears or a loss of hearing occurs ■ new symptoms occur

**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 1 to 2 tablets every 4 hours or 3 tablets every 6 hours, not to exceed 12 tablets in 24 hours
- children under 12 years ■ ask a doctor

**Other information**

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

**Inactive ingredient** corn starch

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

**Distributed by:**  
 ULAI HEALTH LLC,  
 Alexandria, VA 22312

Org. 06/19 9

## ASPIRIN REGULAR STRENGTH

aspirin 325mg tablet

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:73057-365

**Route of Administration** ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

### Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	

### Product Characteristics

Color	white	Score	no score
Shape	ROUND (ROUND TABLET)	Size	10mm
Flavor		Imprint Code	PH033
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73057-365-11	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/28/2019	
2	NDC:73057-365-08	100 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
OTC monograph final	part343	06/28/2019	

**Labeler** - Ulai Health LLC (081181535)

Revised: 1/2022

Ulai Health LLC