

SAFETY COATED ASPIRIN 325 MG REGULAR STRENGTH- aspirin 325mg 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 325mg (NSAID)[†]

[†]nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

- temporarily relieves minor aches and pains due to • minor arthritis pains • headache • toothache • menstrual pain • muscle pain • colds
- or as recommended by a doctor

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 have ever had an allergic reaction to aspirin or any other pain reliever/fever reducer.

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
- redness or swelling is present
- new symptoms occur
- ringing in the ears or loss of hearing occurs

These could be signs 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 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 not exceed 12 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 73057-357-11

Manufactured in the USA

ARTHRITIS PAIN*

‡Compare to the active ingredient in Ecotrin®

Safety Coated

Aspirin 325mg

Regular Strength

PAIN RELIEVER (NSAID)

1000 ENTERIC COATED TABLETS

*for the temporary relief of minor Arthritis Pain

SAFETY COATED ASPIRIN 325 MG REGULAR STRENGTH

aspirin 325mg tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73057-357
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
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	orange	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	PH024
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73057-357-11	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/28/2019	
2	NDC:73057-357-08	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)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)