

PHARBEST ASPIRIN 325MG- aspirin tablet, delayed release
Pharbest Pharmaceuticals, Inc.

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 pain • 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 a nonsteroidal anti-inflammatory drug (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 appear
- 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 to exceed 12 tablets in 24 hours unless directed by a doctor
children under 12 years	ask a doctor

Other information

- store below 20-25⁰ C (68-77⁰ 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 16103-357-11

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

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for the temporary relief of minor Arthritis Pain

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 325 mg (NSAID)
nonsteroidal anti-inflammatory drug

Purpose
Pain reliever

Uses
temporarily relieves minor aches and pains due to: ■ minor arthritis pain ■ headache ■ toothache ■ menstrual pain ■ muscle pain ■ colic ■ 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, etc.) ■ drink 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 or have had any of the following conditions ■ you are taking a prescription drug for disease, liver, cirrhosis, or kidney disease ■ you are taking a diuretic ■ you have asthma ■ gout ■ diabetes ■ arthritis

Ask a doctor or pharmacist before use if you are taking a prescription drug for

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 a loss of hearing occurs

This 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 instructed to do so. If you are pregnant, ask a health professional if they 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 to 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)

This product is manufactured and distributed by Phoebe Pharmaceuticals Inc., owner of Regeneron's Ecotrin®
Manufactured by:
Pharbest Pharmaceuticals, Inc.
Farmingdale, NY 11735

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PHARBEST ASPIRIN 325MG

aspirin tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16103-357
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)	
HYPROMELLOSES (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	10mm
Flavor		Imprint Code	PH024
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16103-357-08	1 in 1 CARTON	09/20/2010	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:16103-357-11	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/20/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	09/20/2010	

Labeler - Pharbest Pharmaceuticals, Inc. (557054835)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Revised: 1/2021

Pharbest Pharmaceuticals, Inc.