

PHARBEST ASPIRIN 325MG- aspirin tablet, delayed release
Contract Pharmacy Services-PA

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.

169 Aspirin Enteric Coated 325 mg

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 • colds • headache • muscle pain • menstrual pain • minor pains of arthritis • toothache
- or as recommended by your 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
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- take more or for a longer time than directed
- have had stomach ulcers or bleeding problems
- have 3 or more alcoholic drinks every day while using this product

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 are taking a diuretic
- you have asthma
- you have high blood pressure, heart disease, liver cirrhosis or kidney disease

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
- any 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 accidental overdose, get medical help or contact a Poison Control Center right away.

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 while symptoms persist. Do not exceed 12 tablets in 24 hours unless directed by a physician.
children under 12 years	consult a physician

Other information

- avoid excess heat and moisture
- store below 25⁰ C (77⁰ F)

Inactive ingredients

croscarmellose sodium, D&C yellow #10 Lake, FD&C red #6, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, polyethylene glycol, propylene glycol, sodium lauryl sulfate,

starch, stearic acid, talc, titanium dioxide, triacetin.

Questions or comments?

Adverse drug event call: 1-866-562-2756

Manufactured in the U.S.A

PHARBEST

Aspirin Regimen

†Compare to the active ingredient in Ecotrin® Regular Strength

#1 Choice of Cardiologists

Aspirin 325mg

Regular Strength

Safety Coated Aspirin 325mg

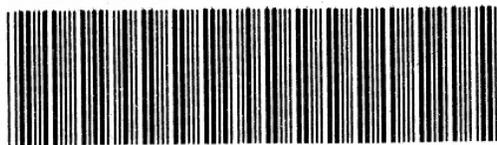
PAIN RELIEVER (NSAID)

NOT FOR HOUSEHOLDS WITH YOUNG CHILDREN

ASPIRIN (ENTERIC COATED)

325 MG

TAB #30



64100010000605

LOT: P11E144

PILL ID: PH 024

EXP: 10/06/12

PHARBEST

Packaged By: Contract Pharmacy Services-PA
125 Titus Ave, Suite #200, Warrington, PA 18976

Directions: drink a full glass of water with each dose; adults and children 12 and over: 1 to 2 tablets every 4 hours, while symptoms persist, not exceed 12 tablets in 24 hours unless directed by a Dr



Store between 68-77°F (20-25°C) avoid excess heat and humidity

Each tablet contains: Aspirin 325 mg

CPS NDC: 67046-169-30

PHARBEST ASPIRIN 325MG

aspirin tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67046-169(NDC:16103-357)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
D&C RED NO. 6 (UNII: 481744AI4O)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

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:67046-169-07	7 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/22/2017	
2	NDC:67046-169-14	14 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/22/2017	
3	NDC:67046-169-15	15 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/22/2017	
4	NDC:67046-169-20	20 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/22/2017	
5	NDC:67046-169-21	21 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/22/2017	
6	NDC:67046-169-28	28 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/22/2017	
7	NDC:67046-169-30	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/22/2017	
8	NDC:67046-169-60	60 in 1 BLISTER PACK; Type 0: Not a Combination Product	09/22/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	09/22/2017	

Labeler - Contract Pharmacy Services-PA (945429777)

Establishment

Name	Address	ID/FEI	Business Operations
Coupler Enterprises		945429777	repack(67046-169)

Revised: 9/2017

Contract Pharmacy Services-PA