

ADULT LOW DOSE ASPIRIN ENTERIC COATED- aspirin 81mg tablet, delayed release

Pharbest Pharmaceuticals, Inc.

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 have asthma
- you are taking a diuretic

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

- 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
- an allergic reaction occurs. Seek medical help right away.
- 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 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 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor
Children under 12 years	consult a doctor

Other information

- store at room temperature (15°-30°C)
- avoid excess heat and moisture

- **Tamper Evident:** do not use if safety seal under cap is broken or missing

Inactive ingredients

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

Questions or comments?

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

PHARBEST

NDC 16103-351-11

Manufactured in the USA

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

Adult Low Dose

Aspirin

ENTERIC COATED

81mg

Aspirin 81 mg

Pain Reliever (NSAID)

EA8

1000 TABLETS

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

PHARBEST **Manufactured in the USA**

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Adult Low Dose

Aspirin

ENTERIC COATED

81mg ASPIRIN 81 mg
Pain Reliever (NSAID)

EA8 **1000 Tablets**

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

This Package for Households Without Young Children

Drug Facts	Purpose
<p>Active ingredient (in each tablet) Aspirin 81 mg (NSAID) <small>nonsteroidal anti-inflammatory drug</small></p> <p>Uses</p> <ul style="list-style-type: none"> ■ 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 <p>Warnings</p> <p>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.</p> <p>Allergy alert: Aspirin may cause a severe allergic reaction which may include</p> <ul style="list-style-type: none"> ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock <p>Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you</p> <ul style="list-style-type: none"> ■ 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 5 or more prescription drugs ■ take more than 1 day while using this product ■ take more or for a longer time than directed <p>Do not use if you are allergic to aspirin or any other pain reliever/fever reducer or if you have ever had an allergic reaction to this product or any of its ingredients</p> <p>Ask a doctor before use if stomach bleeding warning applies to you. You have a history of ulcers or bleeding problems</p> <ul style="list-style-type: none"> ■ you have blood pressure, heart disease, liver cirrhosis or kidney disease ■ you have asthma ■ you are taking a diuretic <p>Ask a doctor or pharmacist before use if you are taking a prescription drug for:</p> <ul style="list-style-type: none"> ■ gout ■ diabetes ■ arthritis <p>Stop use and ask a doctor if you experience any of the following signs of stomach bleeding:</p> <ul style="list-style-type: none"> ■ dark, bloody stools ■ black, tarry stools ■ vomit that looks like coffee grounds <p>Seek medical help right away</p> <ul style="list-style-type: none"> ■ 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 <p>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.</p>	<p>Directions</p> <ul style="list-style-type: none"> ■ 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: Consult a doctor <p>Other information</p> <ul style="list-style-type: none"> ■ store at room temperature (15°-30°C) ■ avoid excess heat and moisture ■ Tamper Evident: do not use if safety seal under cap is broken or missing <p>Inactive ingredients croscarmellose sodium, D&C Yellow #10 Lake, FD&C Yellow #6, hypromellose, lactose, methacrylic acid copolymer, microcrystalline cellulose, silicon dioxide, sodium bicarbonate, sodium lauryl sulfate, starch, talc, titanium dioxide, triacetin, triethyl citrate</p> <p>Questions or comments? (866) 562-2756 Mon - Fri 8AM to 4 PM</p> <p><small>*This product is not manufactured or distributed by Bayer or its subsidiaries. © 2011 Parbest Pharmaceuticals, Inc., Farmingdale, NY 11735</small></p>

ADULT LOW DOSE ASPIRIN ENTERIC COATED

aspirin 81mg tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16103-351
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)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:2) (UNII: XRK36F13ZZ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
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	7mm
Flavor		Imprint Code	EA8
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16103-351-09	120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/20/2019	
2	NDC:16103-351-16	300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/20/2019	
3	NDC:16103-351-11	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/20/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC Monograph Drug	M013	02/20/2019	
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Labeler - Pharbest Pharmaceuticals, Inc. (557054835)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(16103-351) , pack(16103-351) , analysis(16103-351) , label(16103-351)

Revised: 12/2024

Pharbest Pharmaceuticals, Inc.