

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

**Pharbest Pharmaceuticals, Inc.**

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## **Drug Facts**

### **Active ingredient (in each tablet)**

Aspirin 81mg (NSAID)<sup>†</sup>

<sup>†</sup>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

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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

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### **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 16103-351-16**

**Manufactured in the USA**

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

**Adult Low Dose**

**Aspirin**

**ENTERIC COATED**

**81<sup>mg</sup>**

**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  
 ASPIRIN 81 mg  
 Pain Reliever (NSAID)

**EA8** **300 Tablets**

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

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

<b>Drug Facts</b>	<b>Purpose</b> Aspirin 81 mg (NSAID).....Pain reliever nonsteroidal anti-inflammatory drug
<b>Uses</b>	<ul style="list-style-type: none"> <li>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.</li> <li>ask your doctor about other uses for this product</li> </ul>
<b>Warnings</b>	<p><b>Reye's syndrome:</b> 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><b>Allergy alert:</b> Aspirin may cause a severe allergic reaction which may include hives ■ facial swelling ■ asthma (wheezing) ■ shock</p> <p><b>Stomach bleeding warning:</b> 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</p> <p><b>Do not use</b> ■ 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</p> <p><b>Ask a doctor before use if</b> ■ 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</p>

**Peel here for more drug facts**



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Manufactured by:  
 Pharbest Pharmaceuticals, Inc.  
 Farmingdale, NY 11735  
 Org. 04/19

<b>Drug Facts (continued)</b>	<p><b>Ask a doctor or pharmacist before use if you are taking a prescription drug for:</b> ■ gout ■ diabetes ■ arthritis</p> <p><b>Stop use and ask a doctor if</b> ■ 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.</p> <p>■ 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> <p><b>If pregnant or breast-feeding,</b> 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.</p> <p><b>Keep out of reach of children.</b> In case of an accidental overdose, get medical help or contact a Poison Control Center right away.</p>
<b>Directions</b>	<ul style="list-style-type: none"> <li>drink a full glass of water with each dose</li> <li>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.</li> <li>children under 12 years consult a doctor</li> </ul>
<b>Other information</b>	<ul style="list-style-type: none"> <li>store at room temperature (15°-30°C)</li> <li>avoid excess heat and moisture</li> </ul>
<b>Inactive ingredients</b>	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
<b>Questions or comments?</b>	(866) 562-2756 Mon - Fri 8 AM to 4 PM

\*This product is not manufactured or distributed by Bayer, owner of the registered trademark Bayer® Low Dose.

**STOP PEELING**

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)			

<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)
<b>LACTOSE, UNSPECIFIED FORM</b> (UNII: J2B2A4N98G)
<b>METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:2)</b> (UNII: XRK36F13ZZ)
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)
<b>TALC</b> (UNII: 7SEV7J4R1U)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>TRIACETIN</b> (UNII: XHX3C3X673)
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)

### Product Characteristics

<b>Color</b>	yellow (YELLOW COLOR)	<b>Score</b>	no score
<b>Shape</b>	ROUND (ROUND TABLET)	<b>Size</b>	7mm
<b>Flavor</b>		<b>Imprint Code</b>	EA8
<b>Contains</b>			

### 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	

**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)