

## **ADULT LOW DOSE ASPIRIN ENTERIC COATED- aspirin 81mg 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.*

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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 16103-351-11**

**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       |
|--|---------------|
| <b>Active ingredient (in each tablet)</b><br>Aspirin 81 mg (NSAID)<br>Nonsteroidal anti-inflammatory drug  | Pain reliever |
| <b>Uses</b><br>• 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.<br>• ask your doctor about other uses for this product.  |               |
| <b>Warnings</b><br><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.<br><b>Allergy alert:</b> Aspirin may cause a severe allergic reaction which may include hives, facial swelling, asthma (wheezing), shock.<br><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 a stomach or intestinal ulcer, or take aspirin every day while using this product, take more or for a longer time than directed.<br><b>Do not use</b> if you are allergic to aspirin or any other pain reliever/fever reducer you have ever had an allergic reaction to this product or any of its ingredients. |               |
| <b>Ask a doctor before use</b> if stomach bleeding warning applies to you, you have a history of ulcers or bleeding, you are taking blood thinning drugs, high blood pressure, heart disease, liver cirrhosis or kidney disease, you have asthma, or you are taking a diuretic.  |               |
| <b>Ask a doctor or pharmacist before use</b> if you are taking a prescription drug for: • gout • diabetes • arthritis  |               |
| <b>Stop use and ask a doctor</b> if you experience any of the following signs of stomach bleeding: • heartburn • indigestion • stomach pain • black stools • dark or bloody stools • vomit that looks like coffee grounds.<br><b>Seek medical help right away</b> if pain gets worse or lasts more than 10 days, fever gets worse or lasts more than 3 days, redness or swelling is present, or any new symptoms occur or ringing in the ears or loss of hearing occurs.   |               |
| <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. Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.   |               |
| <b>Directions</b><br>• drink a full glass of water with each dose<br>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<br>children under 12 years Consult a doctor  |               |
| <b>Other information</b><br>• store at room temperature (15°-30°C) • avoid excess heat and moisture<br>• <b>Tamper Evident:</b> do not use if safety seal under cap is broken or missing   |               |
| <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 8AM to 4PM  |               |

\*This product is not manufactured or distributed by Bayer or its subsidiaries.  
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# ADULT LOW DOSE ASPIRIN ENTERIC COATED

aspirin 81mg tablet, delayed release

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:16103-351 |
| <b>Route of Administration</b> | ORAL           |                           |               |

## Active Ingredient/Active Moiety

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| <b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN                  | 81 mg           |

## Inactive Ingredients

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| <b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)                              |                 |
| <b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)                             |                 |
| <b>FD&amp;C YELLOW NO. 6</b> (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

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b>                                   | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|--|-----------------------------|---------------------------|
| 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 final | part343                                  | 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) |

Revised: 2/2019

Pharbest Pharmaceuticals, Inc.