

**ASPIRIN- aspirin tablet**  
**CARDINAL HEALTH**

*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)\*

\*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 headaches 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

- facial swelling
- shock
- hives
- asthma (wheezing)

**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.

**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
  - any new symptoms occur
  - pain gets worse or lasts more than 10 days
  - redness or swelling is present
  - ringing in the ears or loss of hearing occurs

These could be signs of a serious illness.

**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 (1-800-222-1222) 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 unless directed by a doctor | not to exceed 48 tablets in 24 hours |
| children under 12 years               | consult a doctor  |                                      |

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**Other information**

- store at room temperature
- save carton for full direction and warnings

**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?**

Adverse drug event call: (866) 562-2756

NDC 49781-097-52

LEADER

†Compare to Bayer® low dose aspirin active ingredient

LEADER

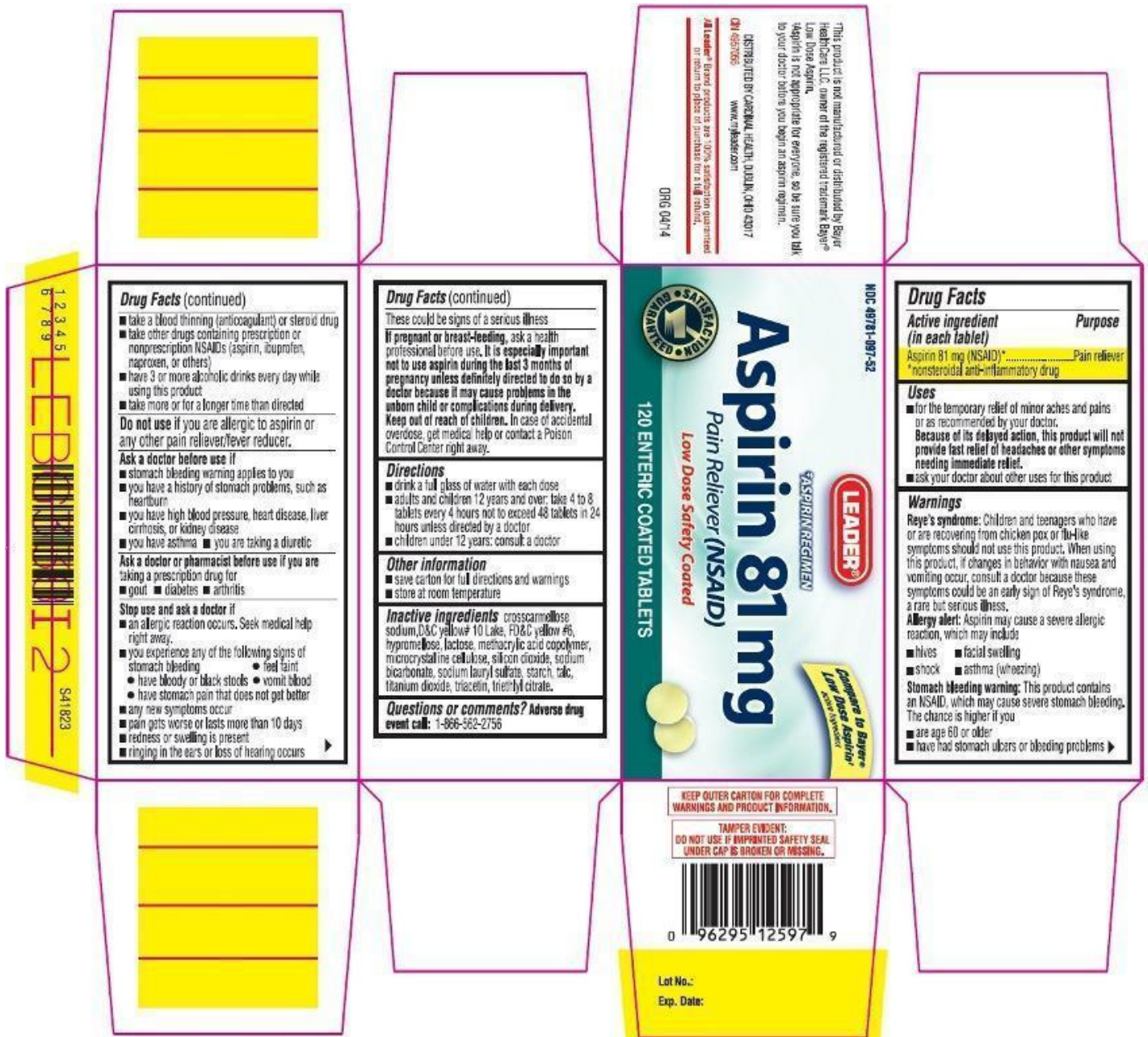
ASPIRIN REGIMEN

Aspirin 81 mg

Pain Reliever (NSAID)

Low Dose Safety Coated

120 ENTERIC COATED TABLETS



## ASPIRIN

aspirin tablet

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:49781-097 |
| 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)                                      |          |
| STARCH, CORN (UNII: O8232NY3SJ)   |          |
| HYPROMELLOSES (UNII: 3NXW29V3WO)  |          |
| LACTOSE (UNII: J2B2A4N98G)  |          |
| METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13) |          |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)                            |          |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO)                                     |          |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J)                                  |          |
| TALC (UNII: 7SEV7J4R1U)   |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                                       |          |
| TRIACETIN (UNII: XHX3C3X673)  |          |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM)                                       |          |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8)                                      |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)  |          |

### Product Characteristics

|          |        |              |          |
|----------|--------|--------------|----------|
| Color    | yellow | Score        | no score |
| Shape    | ROUND  | Size         | 8mm      |
| Flavor   |        | Imprint Code | EA8      |
| Contains |        |              |          |

### Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:49781-097-52 | 1 in 1 CARTON                                      | 09/20/2014           |                    |
| 1 |                  | 120 in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:49781-097-58 | 300 in 1 BOTTLE; Type 0: Not a Combination Product | 09/20/2014           |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part343                                  | 09/20/2014           |                    |

**Labeler** - CARDINAL HEALTH (097537435)

**Registrant** - Pharbest Pharmaceuticals, Inc. (557054835)