

LOW DOSE ASPIRIN- aspirin tablet, chewable
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.

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
- 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
- this product for at least 7 days after tonsillectomy or oral surgery unless directed by a doctor

Ask a doctor before use if

- the 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
- allergic reaction occurs
- 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

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

- **Tamper Evident: Do not use if safety seal under cap is broken or missing**
- store at room temperature (15°-30°C)

- | Product Information | | | |
|---------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:16103-366 |

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	
STARCH, CORN (UNII: O8232NY3SJ)				
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
Product Characteristics				
Color	orange	Score	no score	
Shape	ROUND	Size	8mm	
Flavor	ORANGE	Imprint Code	PH034	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16103-366-05	1 in 1 CARTON	08/22/2007	
1		36 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:16103-366-11	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/22/2007	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part343	08/22/2007		

Labeler - Pharbest Pharmaceuticals, Inc. (557054835)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment

Name	Address	ID/FEI	Business Operations
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Pharbest Pharmaceuticals, Inc.		557054835	analysis(16103-366) , manufacture(16103-366) , pack(16103-366) , label(16103-366)
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Revised: 6/2023

Pharbest Pharmaceuticals, Inc.