

# **ASPIRIN 81MG ENTERIC COATED- aspirin tablet, delayed release**

## **Gendose Pharmaceuticals, LLC**

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### **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.**

### **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 are taking a diuretic
- you have asthma

### **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
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- ringing in the ears or a loss of hearing occurs

### **If pregnant or breast-feeding,**

ask a health professional before use. It is especially important not to use aspirin at 20 weeks or later in 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
- **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 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

### **Inactive ingredients**

Acrycoat, Colloidal Silicon Dioxide, Croscarmellose Sodium, D&C Yellow# 10, Lactose, Microcrystalline Cellulose, Polysorbate 80, Sodium Hydroxide, Talc, Titanium Dioxide, Triethyl Citrate, Yellow Oxide of Iron.

## PRINCIPAL DISPLAY PANEL

**NDC 77333-031-20**

Compares to the active ingredient in BAYER®  
**ASPIRIN LOW DOSE 81mg\***

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

# Aspirin 81mg Tablets Enteric Coated

**UD 150 Tablets (15x10)**



(01) 0 03 77333 031 20 0

 **GenDose®**  
Pharmaceuticals

**NDC 77333-031-20**

## Drug Facts

Active ingredient (in each tablet)	Purpose
Aspirin 81mg (NSAID)**	Pain Reliever
** nonsteroidal anti-inflammatory drug	

### Uses:

• for 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.**

### 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 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 are taking a diuretic • you have asthma

**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 • pain gets worse or lasts more than 10 days • fever gets worse or lasts more than 3 days • redness or swelling is present • new symptoms occur • ringing in the ears or a loss of hearing occurs

**If pregnant or breast-feeding,** ask a health professional before use. It is especially important not to use aspirin at 20 weeks or later in 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 overdose, get medical help or contact a Poison Control Center at 1-800-332-1234.

Poison Control Center (1-800-222-1222) 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 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

**Inactive ingredients:** Acrycoat, Colloidal Silicon Dioxide, Croscarmellose Sodium, D&C Yellow #10, Lactose, Microcrystalline Cellulose, Polysorbate 80, Sodium Hydroxide, Talc, Titanium Dioxide, Triethyl Citrate, Yellow Oxide of Iron.

LB03120X12

ASPIRIN 81MG ENTERIC COATED

aspirin tablet, delayed release

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	
Route of Administration		ORAL	NDC:77333-031	
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)			ASPIRIN	81 mg
Inactive Ingredients				
Ingredient Name				Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
LACTOSE (UNII: J2B2A4N98G)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)				
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)				
Product Characteristics				
Color	yellow	Score	no score	
Shape	ROUND	Size	8mm	
Flavor		Imprint Code	A1	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77333-031-	150 is 1 CARTON	05/01/2025	

1	20	150 in 1 CARTON	05/01/2025	
1	NDC:77333-031-25	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013		05/01/2025	

**Labeler -** Gendose Pharmaceuticals, LLC (080257510)

Establishment			
Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LIMITED		915664486	manufacture(77333-031)