# ASPIRIN- as pirin tablet Preferred 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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## Low Dose Aspirin 81 mg (Delayed-Release Enteric Coated)

## **ACTIVE INGREDIENTS (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.

### **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 very serious illness.

**Allergy alert:** Aspirin may cause a severe allergic reaction which may include:

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

if an allergic reaction occurs, stop use and seek medical help right away.

**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 other pain relievers/fever reducers

### 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:

- anticoagulation (thinning of the blood)
- diabetes
- gout
- 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
- new symptoms occur
- redness or swelling is present
- Ringing in the ears or loss of hearing occurs
- Pain gets worse or lasts for more than 10 days

## 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 specifically 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 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 room temperature
- do not use if imprinted safety seal under cap is broken or missing

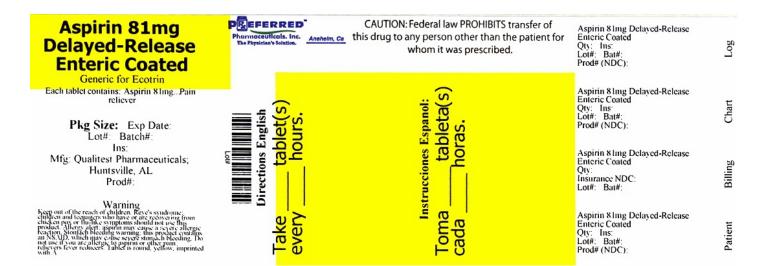
You may report side effects to: 1-888-952-0050.

### **INACTIVE INGREDIENTS**

Anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D&C Yellow 10, iron oxide ochre, methacrylic acid copolymer, microcrystalline cellulose, polysorbate 80, simethicone, sodium hydroxide, sodium laurel sulfate, talc, titanium dioxide, triethyl citrate

## PRINCIPAL DISPLAY PANEL

Pain Reliever



## **ASPIRIN**

aspirin tablet

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:68788- 9671(NDC:0603-0026)
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ASPIRIN (ASPIRIN)	ASPIRIN	81 mg	

Ingredient Name	Strength
CARNAUBA WAX	
ANHYDROUS LACTOSE	
SILICON DIO XIDE	
CROSCARMELLOSE SODIUM	
D&C YELLOW NO. 10	
POLYSORBATE 80	
SO DIUM HYDRO XIDE	
TALC	
TITANIUM DIO XIDE	
TRIETHYL CITRATE	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A	
DIMETHICO NE	
FERRIC O XIDE RED	

Product Characteristics			
Color	yello w	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	A
Contains			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-9671-1	120 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	06/06/2013	

# **Labeler** - Preferred Pharmaceuticals, Inc. (791119022)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Preferred Pharmaceuticals, Inc.		79 1119 0 22	REPACK(68788-9671)	

Revised: 7/2013 Preferred Pharmaceuticals, Inc.