## ASPIRIN LOW DOSE- aspirin tablet, delayed release Preferred Pharmaceuticals Inc.

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Major 44-600A

# Active ingredient (in each tablet)

Aspirin 81 mg (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 serious illness.

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

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

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- take more or for a longer time than directed
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have had stomach ulcers or bleeding problems
- have 3 or more alcoholic drinks every day while using this product
- take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older

#### 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 asthma
- you have a history of stomach problems, such as heartburn
- you are taking a diuretic
- 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:
  - o vomit blood
  - o have bloody or black stools
  - o feel faint
  - o have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs
- new symptoms occur
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present

These could be signs of a serious condition.

### 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 right away.

#### **Directions**

- do not take more than directed
- 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: do not use unless directed by a doctor

#### Other information

- use by expiration date on package
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

#### Inactive ingredients

corn starch, D&C yellow #10, FD&C yellow #6, hypromellose, methacrylic acid, microcrystalline cellulose, polydextrose, polyethylene glycol, shellac wax, silica, simethicone, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triacetin, triethyl citrate

#### Questions or comments?

(800) 616-2471

#### **Principal Display Panel**

**Major**®

Repackaged By: Preferred Pharmaceuticals Inc.

NDC 68788-8334-1

ASPIRIN Low Dose

## PAIN RELIEVER (NSAID)

81 mg

Enteric Coated Safety Coated

**Actual Size** 

#### 1000 Tablets

Compare to the active ingredient in **Bayer**® Low Dose Aspirin†

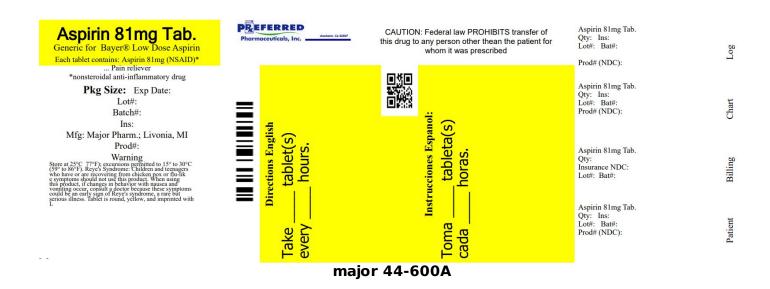
# TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

†This product is not manufactured or distributed by Bayer AG, owner of the registered trademark Bayer® Low Dose Aspirin. 50844 REV0122A60016

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#### MAJOR® PHARMACEUTICALS

17177 N Laurel Park Drive, Suite 233 Livonia, MI 48152 USA M-17 Rev. 05/18 Re-order No. 700939



#### **ASPIRIN LOW DOSE**

aspirin tablet, delayed release

Product	Informati	tion
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:68788-8334(NDC:0904-6751)

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)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
METHACRYLIC ACID (UNII: 1CS02G8656)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POLYDEXTROSE (UNII: VH2XOU12IE)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
SHELLAC (UNII: 46N107B710)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
DIMETHICONE (UNII: 92RU3N3Y1O)			
WATER (UNII: 059QF0KO0R)			

SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics			
Color	yellow	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	L
Contains			

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:68788- 8334-1	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/23/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	343	01/23/2023	

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

## **Registrant - Preferred Pharmaceuticals Inc. (791119022)**

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Preferred Pharmaceuticals Inc.		791119022	REPACK(68788-8334)	

Revised: 2/2024 Preferred Pharmaceuticals Inc.