ADULT LOW DOSE ENTERIC COATED ASPIRIN- aspirin tablet, coated Preferred Pharmaceuticals Inc.

gc 983

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
- ask your doctor about other uses for aspirin

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 your are allergic to aspirin or any other pain reliever/fever reducer.

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you are taking a diuretic
- you have a history of stomach problems, such as heartburn
- you have: -high blood pressure -heart disease -liver cirrhosis -kidney disease asthma

Ask a doctor or pharmacist before use if you are

taking a prescription drug for diabetes, gout or 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
- an allergic reaction occurs. Seek medical help right away
- pain gets worse or lasts more than 10 days
- redness or swelling is present
- fever gets worse or lasts more than 3 days
- any new symptoms occur
- ringing in the ears or loss of hearing occurs

These can 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

- drink a full glass of water with each dose
- swallow whole, do not chew or crush
- do not exceed recommended dose
- adults and children 12 years and older: take 4-8 tablets every 4 hours, as needed, not more than 48 tablets in 24 hours, or as directed by a doctor
- children under 12 years: ask a doctor

Other information

• store at 20-25°C (68-77°F); excursions permitted between 15°C-30°C (59°F-86°F)

Inactive ingredients

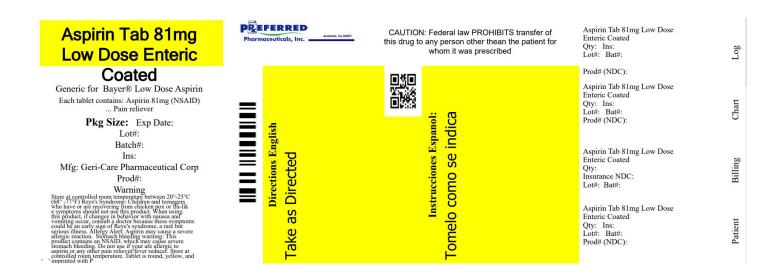
cellulose, croscarmellose sodium, D&C Yellow #10 Lake, lactose monohydrate, methacrylic acid co-polymer, PEG, polacrilin potassium, polyvinyl alcohol, silica, sodium lauryl sulfate, soya powder, talc, titanium dioxide, triethyl citrate

Relabeled By: Preferred Pharmaceuticals Inc.

Questions or comments?

1-800-540-3765

package label



ADULT LOW DOSE ENTERIC COATED ASPIRIN

aspirin tablet, coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-8565(NDC:57896-983)	
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			
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
POLACRILIN POTASSIUM (UNII: 0BZ5A00FQU)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ 1374NL9E)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

SOYBEAN (UNII: L7HT8F1ZOD)

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

SODIUM LAURYL SULFATE (UNII: 368GB5141J)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

TRIETHYL CITRATE (UNII: 8Z96QXD6UM)

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

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:68788- 8565-8	120 in 1 BOTTLE; Type 0: Not a Combination Product	01/12/2024		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M013	01/12/2024		

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment				
Name	Address	ID/FEI	Business Operations	
Preferred Pharmaceuticals Inc.		791119022	REPACK(68788-8565)	

Revised: 1/2024 Preferred Pharmaceuticals Inc.