ASPIRIN- aspirin 81mg tablet, delayed release
America's Pharmacy Source LLC

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. **Because of its delayed action, this product will not provide fast relief of headache or other symptoms needing immediate relief.**
- 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
- 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 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 •an allergic reaction occurs. Seek medical help right away.
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 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 overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

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 or as directed by a doctor
children under 12 years	ask a doctor

Other information
- store at room temperature (15 ^{0}-30 ^{0}C)
- avoid excess heat and moisture

Inactive ingredients

croscarmellose sodium, D&C yellow# 10, FD&C yellow #6, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, polyethylene glycol, sodium lauryl sulfate, starch, stearic acid, talc, titanium dioxide

Questions or comments?

(866) 562-2756 (Mon- Fri 8 AM to 4 PM EST)

AMERICA'S PHARMACY SOURCE

COMPARE TO ACTIVE

INGREDIENT IN

BAYER ® LOW DOSE

LOW STRENGTH ASPIRIN

Aspirin

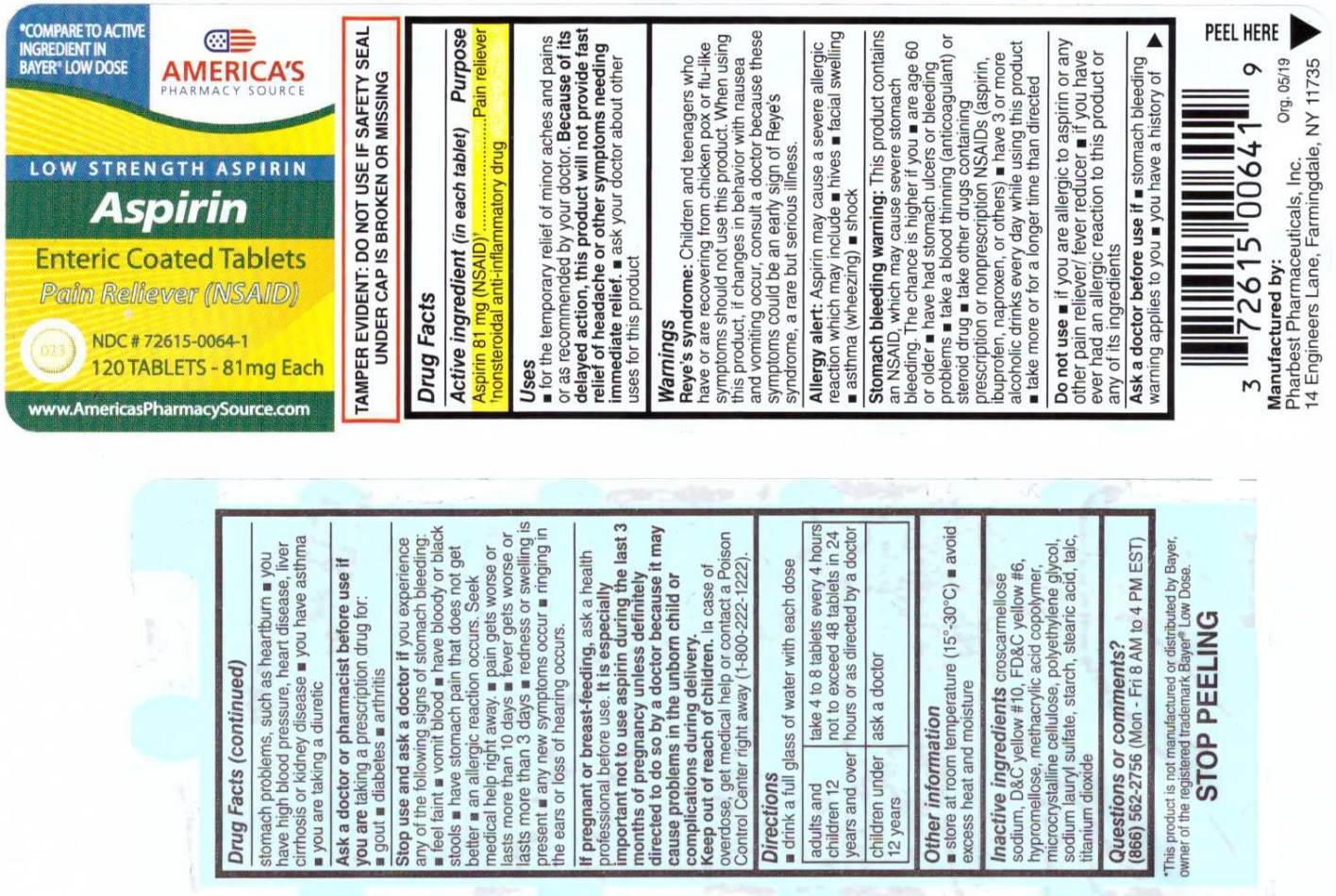
Enteric Coated Tablets

Pain Reliever *(NSAID)*

NDC# 72615-0064-1

120 TABLETS - 81mg Each

www.AmericasPharmacySource.com



ASPIRIN

aspirin 81mg tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72615-0064
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**
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics			
Color	yellow	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	PH;023
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:72615-0064-1	120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/02/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	10/02/2019	

Labeler - America's Pharmacy Source LLC (116701866)

Registrant - America's Pharmacy Source LLC (116701866)

Establishment

Name	Address	ID/FEI	Business Operations

Pharbest Pharmaceuticals, Inc.		557054835	manufacture(72615-0064) , analysis(72615-0064) , repack(72615-0064) , relabel(72615-0064)

Revised: 11/2019 America's Pharmacy Source LLC