

ASPIRIN 81 MG ENTERIC COATED- aspirin tablet
Marlex 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.

Aspirin 81mg Enteric Coated Tablets

ASPIRIN 81MG TABLETS
Marlex Pharmaceuticals, Inc.

Active ingredient (in each tablet)

Purpose

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

Aspirin 81 mg Tablets

Uses

- Temporarily relieves minor aches and pains.
- For other uses, see your doctor, but do not use for more than 10 days without consulting your doctor because serious side effects may occur

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:

- 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

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
- You have not been drinking fluids
- You have lost a lot of fluid due to vomiting or diarrhea

Ask a doctor or a pharmacist before use if you are

- Taking a prescription drug for diabetes, gout, or arthritis
- Under a doctor's care for any serious condition
- Taking any other drug

Stop use and ask a doctor if

- You experience any of the following signs of stomach bleeding
- Feel faint
- Have bloody or black stools
- Vomit blood
- Have stomach pain that does not get better
- Pain gets worse or lasts more than 10 days
- Redness or swelling is present in the painful area
- Any new symptoms appear
- 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 during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problem 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 25°C (77°F) excursions permitted between 15-30°C (59-86°F)
- Use by expiration date on package

Inactive Ingredients:

Microcrystalline Cellulose, Croscarmellose Sodium, Pregelatinized Starch, Stearic Acid, Colloidal Silicon Dioxide, Methacrylic Acid and Ethyl Acrylate Co-Polymer, Triethyl Citrate, Talc, Titanium Dioxide, D&C Yellow #10, FD&C Yellow #6

Questions?

Adverse Drug Event Call: **(800) 222-1222**

Manufactured for & Distributed by:

Marlex Pharmaceuticals, Inc.

New Castle, DE 19720

Rev: 12/19 HP

PRINCIPAL DISPLAY PANEL

ASPIRIN

81mg

120 Tablets

The image shows the principal display panel for Aspirin 81mg Tablets. The panel is rectangular with rounded corners and a white background. At the top left, it displays the NDC number 10135-0689-62. The Marlex Pharmaceuticals, Inc. logo is prominently featured, with the word 'MARLEX' in a blue, stylized font and 'PHARMACEUTICALS, INC.' in a smaller, black font below it. The product name 'ASPIRIN' is written in large, bold, black letters, with '81mg' in a slightly smaller font below it. A green banner at the bottom left contains the text: 'LOW STRENGTH 81mg ASPIRIN (NSAID) Enteric Coated 1 1/4 gr. (81 mg) each Analgesic SEE NEW WARNINGS INFORMATION 120 Tablets'. Below this banner, there is a small note: '**Compare to the active ingredient in BAYER® Low Dose'. On the right side of the panel, there is a barcode and the text 'Distributed by: Marlex Pharmaceuticals, Inc. New Castle, DE 19720 Rev 12/19 HP'. Below the barcode, the text 'N 3 10135 68962 0' is printed. A vertical line separates the product information from the 'Drug Facts' section. The 'Drug Facts' section is enclosed in a black border and contains the following information: 'Purpose: Pain reliever', 'Active ingredient (in each tablet): Aspirin 81 mg (NSAID)*', 'Uses: temporarily relieves minor aches and pains; for other uses, see your doctor, but do not use for more than 10 days without consulting your doctor because serious side effects may occur', 'Warnings: 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: 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, ...'. At the bottom right of the panel, there is a small orange triangle with the text 'PEEL HERE FOR MORE DRUG FACTS'. The entire panel is framed by a red dashed line.

ASPIRIN 81 MG ENTERIC COATED

aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10135-689
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
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	5mm
Flavor		Imprint Code	A1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10135-689-62	120 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	02/01/2020	

Labeler - Marlex Pharmaceuticals Inc (782540215)

Revised: 9/2021

Marlex Pharmaceuticals Inc