

ASPIRIN- aspirin tablet
Marlex Pharmaceuticals Inc.

ASPIRIN 81MG TABLETS

Drug Fact

Active ingredient (in each tablet)

Aspirin 81mg (NSAID*)

*nonsteroidal anti-inflammatory drug

Purpose

Pain Reliever

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
- Fever gets worse or lasts more than 3 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:

Corn Starch, Pregelatinized Starch, Povidone, Microcrystalline Cellulose, Stearic Acid, Colloidal Silicon Dioxide, Methacrylic Acid Co-Polymer, Triethyl Citrate, Talc, Titanium Dioxide, Silica, Sodium bicarbonate, Sodium lauryl sulfate, D&C Yellow #10, Hypromellose, Triacetin

Questions?

Adverse Drug Event Call: **(888) 582 1953** or Email: drugsafety@marlexpharm.com

PRINCIPAL DISPLAY PANEL

Distributed by:

Marlex Pharmaceuticals, Inc.


New Castle, DE 19720

Rev.1 09/21 AA

www.marlexpharm.com

NDC 10135-0729-62


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ASPIRIN
81mg

LOW STRENGTH 81mg ASPIRIN (NSAID)
Enteric Coated
1 1/4 gr. (81 mg) each Analgesic
SEE NEW WARNINGS INFORMATION
120 Tablets

** Compare to the active ingredient in BAYER® Low Dose



3 10135 72962 3

TEMPERATURE SENSITIVE SEAL OVER THE MOUTH OF THE BOTTLE IS GUT, TORN, BROKEN OR MISSING

This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Bayer® Low Dose.

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Marlex Pharmaceuticals, Inc.
New Castle, DE 19720
Rev. 1 09/21 AA
www.marlexpharm.com

Drug Facts	Active ingredient (in each tablet)	Purpose
<p>Aspirin 81 mg (NSAID)*, Pain reliever</p> <p>* nonsteroidal anti-inflammatory drug</p> <p>Uses</p> <ul style="list-style-type: none"> 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 <p>Warnings</p> <p>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.</p> <p>Allergy alert: Aspirin may cause a severe allergic reaction, which may include: <ul style="list-style-type: none"> hives facial swelling shock asthma (wheezing) </p> <p>Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: <ul style="list-style-type: none"> 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, </p>	<p>Aspirin 81 mg (NSAID)*, Pain reliever</p>	<p>Pain reliever</p>

PEEL HERE FOR MORE DRUG FACTS

<p>Directions</p> <ul style="list-style-type: none"> 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 <p>Other information</p> <ul style="list-style-type: none"> store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) use by expiration date on package <p>Inactive Ingredients Corn Starch, Pregelatinized Starch, Povidone, Microcrystalline Cellulose, Colloidal Silicon dioxide, Stearic Acid, Methacrylic Acid Copolymer, Talc, Titanium Dioxide, Triethyl Citrate, Silica, Sodium Bicarbonate, Sodium Lauryl Sulfate, D&C Yellow #10, Hypromellose, Triacetin</p> <p>Questions? Adverse Drug Event Call: (888) 582-1953 or email: drugsafety@marlexpharm.com</p>	<p>Drug Facts (continued)</p> <p>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</p> <p>Do not use • if you are allergic to aspirin or any other pain reliever/fever reducer</p> <p>Ask a doctor before use if</p> <ul style="list-style-type: none"> 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 <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> taking a prescription drug for diabetes, gout, or arthritis under a doctor's care for any serious condition taking any other drug <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> you experience any of the following signs of stomach bleeding: <ul style="list-style-type: none"> 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 fever gets worse or lasts more than 3 days redness or swelling is present in the painful area any new symptoms appear ringing in the ears or a loss of hearing occurs <p>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.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>
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STOP PEELING

ASPIRIN

aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10135-729
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
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRIACETIN (UNII: XHX3C3X673)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	S;17
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10135-729-62	120 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	09/01/2021	

Labeler - Marlex Pharmaceuticals Inc. (782540215)

Revised: 10/2023

Marlex Pharmaceuticals Inc.