

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 USP 81mg Enteric Coated Tablet

ASPIRIN 81 MG ENTERIC COATED- aspirin tablet Reliable 1 Laboratories LLC

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Aspirin USP 81mg Enteric Coated Tablet

Drug Facts

Active ingredients (in each tablet)

Aspirin 81 mg (NSAID*)

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

- temporarily relieves minor aches and pains

Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief.

- ask your doctor about other uses for enteric-coated 81 mg 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 any include:

- Hives
- facial swelling shock
- asthma (wheezing)

Somach bleeding warning: This product contains 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 pharmacist before use if you are

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

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:

- 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
- new symptoms occur
- ringing in the ears or a loss of hearing occurs

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 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.

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

anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D&C yellow #10 aluminum lake, iron oxide ochre, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, starch, talc, titanium dioxide, triethyl citrate

Questions or comments?

call 516-341-0666, 8:30 am - 4:30 pm ET, Monday – Friday

PRINCIPAL DISPLAY PANEL

NDC 10135-0173-62

Aspirin

81mg

Low Strength 81 mg ASPIRIN
(NSAID)

Enteric Coated

1 ¼ gr. (81 mg) each Analgesic

NDC 10135-0173-62

MARLEX
PHARMACEUTICALS, INC.

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

This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Bayer® Low Dose.
Distributed by:
Marlex Pharmaceuticals, Inc.
New Castle, DE 19720
Rev. 3/8/18 TOL

Drug Facts

Active ingredient (in each tablet)
Aspirin 81 mg (NSAID*)

Purpose
Pain relief
*nonsteroidal anti-inflammatory drug

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)

Do not use

- if you are allergic to aspirin or any other pain reliever/fever reducer
- if you are allergic to aspirin or any other pain reliever/fever reducer
- if you have a history of stomach problems, such as heartburn
- if you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- if you are taking a diuretic
- if you have asthma
- if you have not been drinking fluids
- if you have lost a lot of fluid due to vomiting or diarrhea

Ask a doctor or 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 problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of over dose, 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 Anhydrous lactose, Carnauba Wax, Colloidal Silicon Dioxide, Croscarmellose Sodium, D&C Yellow #10 Aluminum Lake, Iron Oxide Ochre, Methacrylic Acid and Ethyl Acrylate Copolymer, Microcrystalline Cellulose, Polysorbate 80, Simethicone, Sodium Hydroxide, Sodium Lauryl Sulfate, Starch, Talc, Titanium Dioxide, Triethyl Citrate.

Questions? Adverse Drug Event Call: (800) 222-1222

STOP PEELING

PEEL HERE FOR MORE DRUG FACTS

ASPIRIN 81 MG ENTERIC COATED

aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10 135-173
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)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TALC (UNII: 7SEV7J4R1U)	
IRON (UNII: E1UOL152H7)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	YELLOW	Score	no score
Shape	ROUND	Size	5mm
Flavor		Imprint Code	Heart
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 135-173-62	120 in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	08/01/2018	

