

ASPIRIN - aspirin tablet, extended release
Gemini Pharmaceuticals, Inc. dba Plus Pharmaceuticals

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 81 mg (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
- asthma (wheezing)
- shock

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or non prescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- take more or for a longer time than directed
- are age 60 or older
- have 3 or more alcoholic drinks every day while using this product

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 have asthma
- you are taking a diuretic
- 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

- you experience any of the following signs of stomach bleedin

feel faint

vomit blood

have bloody or black stools

- 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 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

- **Do not use if imprinted safety seal under cap is broken or missing.**
- store at 25⁰C (77⁰ F) excursions permitted between 15⁰-30⁰C (59⁰-86⁰ F)

Inactive ingredients:

Anhydrous Lactose, Carnauba Wax, Colloidal Silicon Dioxide, Croscarmellose Sodium, D and C Yellow #10 Aluminum Lake, Iron Oxide Ochre, Methacrylic Acid Copolymer, Microcrystalline Cellulose, Polysorbate 80, Simethicone, Sodium Hydroxide, Sodium Lauryl Sulfate, Talc, Titanium

Dioxide, Triethyl Citrate.

Questions?

If you have any questions or comments, or to report an adverse event, please contact (800) 795-9775.

Principal Display Panel

PlusPHARMA

ASPIRIN

81 mg

NSAID

PAIN RELIEVER

LOW DOSE ASPIRIN REGIMEN

- Safety Coated-Enteric Coated
- Delayed Release Aspirin Tablets
- Small, Easy-to-Swallow 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.

120 TABLETS

- 81 mg each

PlusPHARMA™

ASPIRIN

NSAID 81 mg

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Drug Facts (continued on back)

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Rev 12/12

Lot#

Exp. Date

PEEL
HERE



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Drug Facts (continued)

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Distributed By: Plus Pharma, Commack, NY 11725

ASPIRIN

aspirin tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51645-717	
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		
	ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)			
	CARNAUBA WAX (UNII: R12CBM0EIZ)			
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
	CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
	D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
	CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
	POLYSORBATE 80 (UNII: 6OZP39ZG8H)			
	SODIUM HYDROXIDE (UNII: 55X04QC32I)			
	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 (YELLOW)	Size	7mm	
Flavor		Imprint Code	RAISED;HEART	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51645-717-08	120 in 1 BOTTLE, PLASTIC		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part343	01/10/2013		

Labeler - Gemini Pharmaceuticals, Inc. dba Plus Pharmaceuticals (055942270)

Registrant - Gemini Pharmaceuticals, Inc. dba Plus Pharmaceuticals (055942270)