ASPIRIN ADULT LOW DOSE- acetylsalicyclic acid tablet, delayed release
Medline Industries

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.

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985 Aspirin 81mg EC tablets

Active ingredient (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 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 have ever had an allergic reaction to 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 fluids 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.
- 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 for more than 10 days
- redness or swelling is present
- new symptoms occur
- ringing in the ears or 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 older: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless otherwise 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°-68°F)
- use by expiration date on package

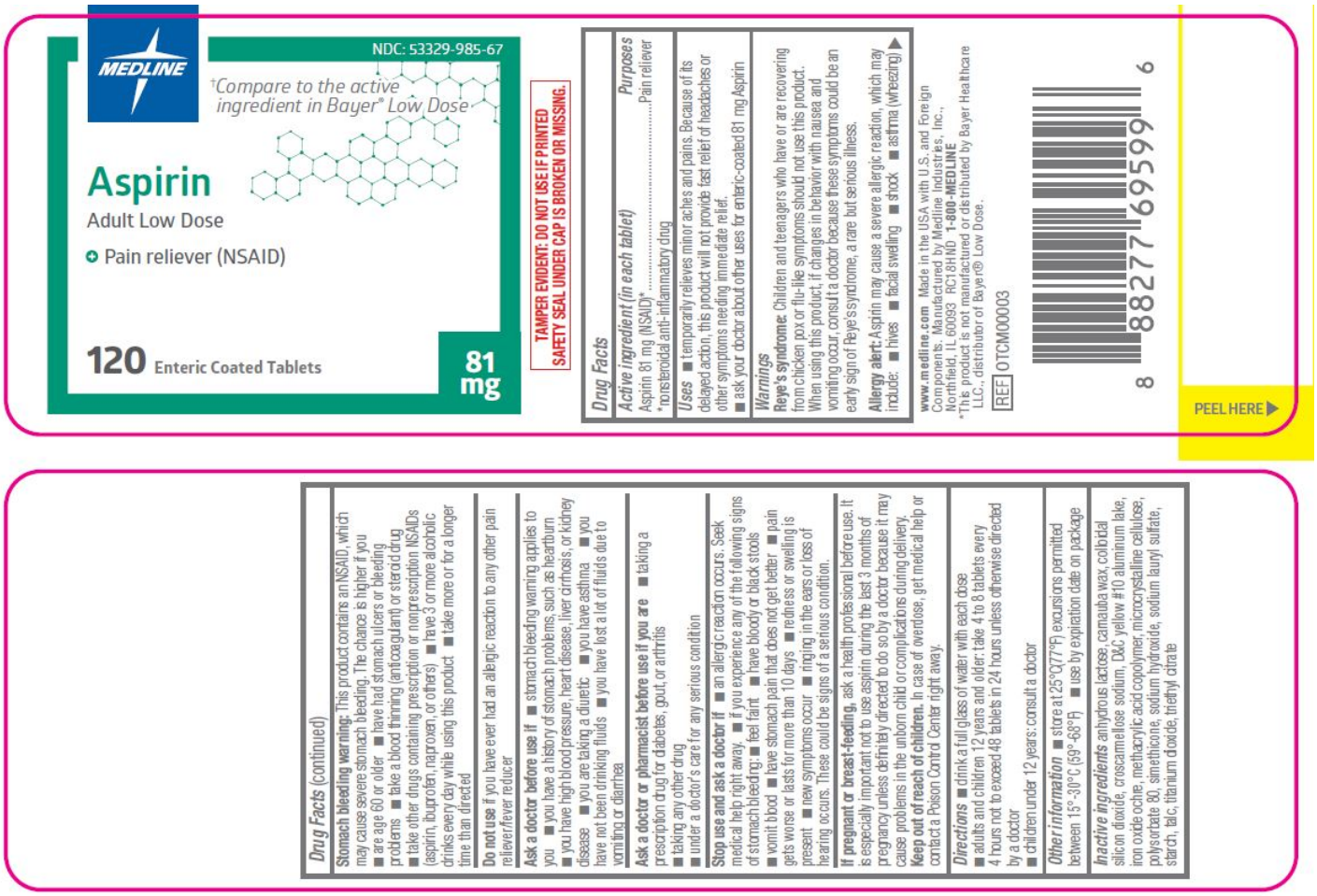
Inactive ingredients

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

www.medline.com Made in the USA with U.S. and Foreign
Components. Manufactured by Medline Industries, Inc.,

Northfield, IL 60093 RC18HND **1-800-MEDLINE**
*This product is not manufactured or distributed by Bayer Healthcare LLC., distributor of Bayer® Low Dose.

Package Label



ASPIRIN ADULT LOW DOSE

acetylsalicyclic acid tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53329-985
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**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	

Product Characteristics

Color	yellow	**Score**	score with uneven pieces
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	embossed;heart
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-985-67	120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/25/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	06/25/2018	

Labeler - Medline Industries (025460908)

Establishment

Name	Address	ID/FEI	Business Operations
Time Cap Labs		037052099	manufacture(53329-985)

Establishment

Name	Address	ID/FEI	Business Operations
Medline Industries		079800021	repack(53329-985)

Revised: 12/2019 Medline Industries