# 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

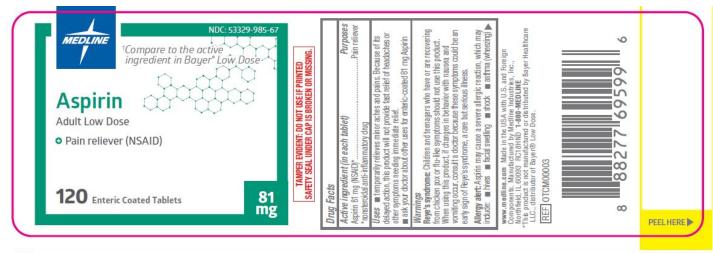
## Inactive ingredients

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



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s (continued)	Ing warning: This product or restormato The chi older = have had stomach e a blood thimning (antioaag gs containing prescription or an, naproxen, or others) = th while using this product = ed	Do not use if you have ever had an allengic reaction to any other pain reliever/fever reducer	Ask a doctor before use if a stornach bleeding warning applies to you myou have a history of stornach problems, such as heartburn myou have high blood pressure, heart disease, liver cirrhosis, or kidney disease myou are taking a diutetic myou have asthma myou have not ben drinking fluids myou have lost a lot of fluids due to voriging or diarthe	Ask a doctor or pharmacist before use if you are prescription drug for dabetes, gout, or artitritis making any other drug under a doctor's care for any serious condition	Stop use and ask a doctor if an allergic reaction cocurs. Seek medical help right away. If you experience any of the following signs of stormach bleeding: The fairt Three bloody or hack stools a worm the bood In have shoredon pain that does not get better. If pain gets worse or lasts for more than 10 days. The ears or loss of present Thew shoredon that body are induced 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 asplinn during the bast 3 months of pregnancy unless defined viewed bo so by a boto become are it may cause problems in the unborn child or complications during delivery. Cause problems in the unborn child or complications during delivery.	Directions = drink a full glass of water with each dose = adults and children 12 years and older: take 4 to 8 tablets every + trous not to exceed 48 tablets in 24 hours unless otherwise directed by a doctor = didferunder 12 years: consult a doctor	formation store at 25°Q77°F) excursions permitted 15°-30°C (59°-68°F) = use by expiration date on package	Inactive ingredients anhydrous lactoes, camauba wax, colbidal silicon dioxide, croscarmellose sodium, D&C yellow #10 aluminum lake, ton oxide oche, methazylic actio congriner, microcrystalline colluices, polysorbate 80, simethicone, sodium hydroide, sodium lauyi suffate, starch, talc, tamium doode, triefly ditate
Drug Facts	Stomach bleed may cause seve are age 60 or problems = tak take other dru (aspirin, ibuprofé (aspirin, ibuprofé time than directi	Do not use if you hav reliever/fever reducer	Ask a doctor bef you have hight ■ you have hight disease ■ you a have not been dri vorniting or diarrh	Ask a doctor or pharm prescription drug for da taking any other drug under a doctor's care	Stop use and medical help of stomachbl womit bbood gets worse or present me	If pregnant o is especially ii pregnancy un pregnancy un cause problem cause out of n contact a Pois	Directions I adults and 4 hours not to by a doctor children un	Other information between 15°-30°C (59	Inactive ing silicon dioxide iron oxide och polysorbate 8 starch, talc, ti starch, talc, ti

# ASPIRIN ADULT LOW DOSE

acetylsalicyclic acid tablet, delayed release

Product Information							
HUMAN OTC DRUG	Item Code (S	Source)	NDC:53329-985				
oute of Administration ORAL							
Active Inque diant/Active Meister							
Active Ingredient/Active Moiety							
Ingredient Name							
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)				1 mg			
Inactive Ingredients							
Ingredient Name							
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)							
	ORAL ety dient Name V - UNII:R16CO5Y76E) Ingredient Name	ORAL ety dient Name Ingredient Name	ORAL ety dient Name I court (court) Basis of Stress I court (court) Basis of Stress Aspirin Ingredient Name	ORAL ety dient Name Basis of Strength ASPIRIN 8 Ingredient Name			

(011	II: 92RU3N3Y1O)				
SO DIUM HYDRO XI	<b>DE</b> (UNII: 55X04QC32	21)			
CARNAUBA WAX (U	UNII: R12CBM0EIZ)				
D&C YELLOW NO.	. <b>10</b> (UNII: 35SW5USC	(3G)			
METHACRYLIC AC	ID - ETHYL ACRYLA	ATE COPOLYMER (1:1)	TYPE A (UNII: N)	K76LV5T8J)	
CELLULOSE, MICR	ROCRYSTALLINE (U	INII: OP1R32D6 1U)			
POLYSORBATE 80	(UNII: 6OZP39ZG8H	)			
SODIUM LAURYL S	SULFATE (UNII: 3680	GB5141J)			
STARCH, CORN (UI	NII: O8232NY3SJ)				
<b>ΓALC</b> (UNII: 7SEV7J	J4R1U)				
<b>FITANIUM DIO XID</b>	E (UNII: 15FIX9V2JP)				
FERRIC OXIDE YEI	LLOW (UNII: EX438C	2MRT)			
<b>FRIETHYL CITRAT</b>	E (UNII: 8Z96QXD6U	J <b>M</b> )			
ANHYDRO US LACT	rose (UNII: 35Y5LH9	PMK)			
- 1 - 61					
Product Charac					
Color	yellow Score score with uneven pieces				
Shape	ROUND Size 7mm				
Flavor		Imprint Code	sed;heart		
Contains					
Contains					
Packaging	P	ackage Description		Marketing Start Date	Marketing End Date
Packaging # Item Code		<b>'ackage Description</b> LASTIC; Type 0: Not a Co	mbination	-	-
Packaging # Item Code NDC:53329-985-	120 in 1 BOTTLE, P		mbinatio n (	Date	•
Fackaging       Item Code       NDC:53329-985- 67	120 in 1 BOTTLE, P Product		mbination (	Date	-
NDC:53329-985-	120 in 1 BOTTLE, P Product			Date	-

Labeler - Medline Industries (025460908)

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

# Establishment

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