# ASPIRIN ENTERIC COATED LOW DOSE- aspirin tablet, delayed release Walgreen Company

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Walgreens 44-645

### Active ingredient (in each tablet)

Aspirin 81 mg (NSAID)\*
\*nonsteroidal anti-inflammatory drug

### **Purpose**

Pain reliever

### Uses

for the temporary relief of minor aches and pains or as recommended by your doctor. Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief.

### 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

- take more or for a longer time than directed
- take a blood thinning (anticoagulant) or steroid drug
- have had stomach ulcers or bleeding problems
- have 3 or more alcoholic drinks every day while using this product
- are age 60 or older
- 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 have ever had an allergic reaction to this product or any of its ingredients

### Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you are taking a diuretic
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you have asthma

### Ask a doctor or pharmacist before use if you are

taking a prescription drug for

- gout
- diabetes
- arthritis

### 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:
  - have bloody or black stools
  - feel faint
  - vomit blood
  - have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

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 at 20 weeks or later in 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**

- do not take more than directed
- 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: do not use unless directed by 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

colloidal anhydrous silica, corn starch, FD&C red #40, FD&C yellow #6, hypromellose, methacrylic acid, microcrystalline cellulose, polydextrose, polyethylene glycol, shellac wax, simethicone, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triacetin, triethyl citrate

### Questions or comments?

1-800-426-9391

### Principal Display Panel

**VALUE SIZE** 

NDC 0363-6450-14

### Walgreens

Compare to the active ingredient in St. Joseph® Low Dose 81 mg Aspirin††

**EASY-OPEN** 

### **Aspirin 81**

81 mg / PAIN RELIEVER (NSAID)

### Low Dose Enteric-Coated

### 500

**TABLETS** 

**ACTUAL SIZE** 

**HEART** 

**HEALTH\*\*** 

\*\*Talk to your doctor or other healthcare provider before using this product for your heart.

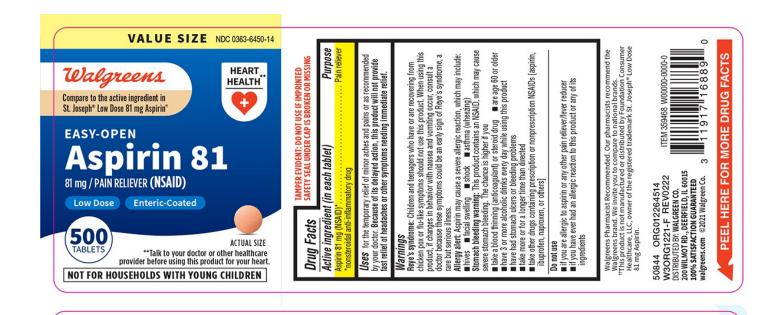
### NOT FOR HOUSEHOLDS WITH YOUNG CHILDREN

# TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

††This product is not manufactured or distributed by Foundation Consumer Healthcare, LLC, owner of the registered trademark St. Joseph® Low Dose 81 mg Aspirin.

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# Adhesive Area

STOP PEELING

Questions or comments? 1-800-426-9391

Inactive ingredients colloidal anhydrous silica, corn starch, FD&C red #40, FD&C yellow #6, hypromellose, methacrylic acid, microcrystalline cellulose, polydextrese, polyethylene glyca, Shellace wax, smethicone, codium bicarbonate, sodium lauryl sulfate, talc, tianium dioxide, triacetin,

Other information ■ use by expiration date on package ■ store at 25°C (77°F); excursions permitted between 15\*-30°C (59\*-86°F)

■ drink a full glass of water with each dose
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■ children under 12 years: do not use unless directed by a doctor

problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or

Directions

do not take more than directed

redness or swelling is present

These could be signs of a serious condition.

ringing in the ears or a loss of hearing occurs
 pain gets worse or lasts more than 10 days
 fever gets worse or lasts more than 3 days

■ have bloody or black stools ■ feel faint ■ have stomach pain that does not get better

■ vomit blood

an allergic reaction occurs. Seek medical help right away.
 you experience any of the following signs of stomach bleeding:

Stop use and ask a doctor if

Ask a doctor or pharmacist before use if you are taking a prescription drug for gout diabetes arthrits

■ you are taking a diuretic ■ you have asthma

■ 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

Ask a doctor before use if **Drug Facts** (continued)

Walgreens 44-645

### **ASPIRIN ENTERIC COATED LOW DOSE**

aspirin tablet, delayed release

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-6450
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) STARCH, CORN (UNII: O8232NY3SJ) FD&C RED NO. 40 (UNII: WZB9127XOA) FD&C YELLOW NO. 6 (UNII: H77VEI93A8) HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) METHACRYLIC ACID (UNII: 1CS02G8656) MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) POLYDEXTROSE (UNII: VH2XOU12IE) POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) **SHELLAC** (UNII: 46N107B710) **DIMETHICONE** (UNII: 92RU3N3Y10) WATER (UNII: 059QF0KO0R) **SODIUM BICARBONATE** (UNII: 8MDF5V39QO) **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) TALC (UNII: 7SEV7J4R1U) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) TRIACETIN (UNII: XHX3C3X673) TRIETHYL CITRATE (UNII: 8Z96QXD6UM)

Product Characteristics				
Color	pink	Score	no score	
Shape	ROUND	Size	6mm	
Flavor		Imprint Code	L	
Contains				

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363- 6450-14	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/25/2014	
2	NDC:0363- 6450-07	1 in 1 CARTON	07/25/2014	07/08/2018
2		36 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0363- 6450-12	1 in 1 CARTON	07/25/2014	09/21/2017
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0363- 6450-60	1 in 1 CARTON	07/25/2014	04/27/2022
4		180 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0363- 6450-32	1 in 1 CARTON	07/25/2014	04/22/2023
5		120 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information					
Marketing	Application Number or Monograph	Marketing Start	Marketing End		
Category	Citation	Date	Date		

# Labeler - Walgreen Company (008965063)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		038154464	pack(0363-6450)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(0363-6450)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867894	manufacture(0363-6450)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		868734088	manufacture(0363-6450)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		967626305	pack(0363-6450)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(0363-6450)

Revised: 8/2023 Walgreen Company