

## ASPIRIN ENTERIC COATED LOW DOSE- aspirin tablet, coated

Walgreen Company

*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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**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:
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
  - feel faint
- ringing in the ears or a loss of hearing occurs
- pain gets worse or lasts more than 10 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 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 (1-800-222-1222) 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: 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)
- see end flap for expiration date and lot number

***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***

***Walgreens***

NDC 0363-6450-60

*Compare to St. Joseph® Low Dose  
81 mg Aspirin active ingredient<sup>††</sup>*

**Aspirin 81**

**81 mg / PAIN RELIEVER (NSAID)**

**LOW DOSE**

**180 ENTERIC -COATED  
TABLETS**

**ACTUAL SIZE**

**HEART  
HEALTH\*\***

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

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

**DOES NOT CONTAIN GLUTEN**

Walgreens pharmacist Recommend  
Walgreens Pharmacist Survey

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

50844 ORG031864560

**DISTRIBUTED BY: WALGREEN CO.  
200 WILMOT RD., DEERFIELD, IL 60015**

**100% SATISFACTION GUARANTEED**

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Walgreens 44-645

## ASPIRIN ENTERIC COATED LOW DOSE

aspirin tablet, coated

### Product Information

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: 46N107B71O)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
WATER (UNII: 059QF0KO0R)	

## Product Characteristics

Color	PINK	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	L
Contains			

## Packaging

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

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	07/25/2014	

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(0363-6450)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	MANUFACTURE(0363-6450) , PACK(0363-6450)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(0363-6450)

Revised: 8/2019

Walgreen Company