# LOW DOSE ASPIRIN- aspirin tablet, coated Topco Associates

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**Drug Facts** 

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.
- ask your doctor about other uses for safety 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 are allergic to aspirin or any other pain reliever/fever reducer.
- if you have ever had an allergic reaction to his 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 have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- 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:
  - o feel faint
  - vomit blood
  - have bloody or black stool
  - have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- fever get worse or lasts more than 3 days
- redness or swelling is present
- ringing in the ears or loss of hearing occurs
- 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 during the last 3 month 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: consult a doctor

#### Other information

• store between 15-30°C (59-86°F)

### Inactive ingredients

croscarmellose sodium, D&C yellow #10, lactose monohydrate, methacrylic acid, microcrystalline cellulose 102, polacrilin potassium, polyethylene glycol 6000, polyvinyl alcohol, purified talc, silicon dioxide, sodium lauryl sulfate, soybean, titanium dioxide, triethyl citrate

#### **Questions or comments?**

Call toll free 1-888-423-0139

### **Principal Display Panel**

COMPARE TO BAYER® LOW DOSE ASPIRIN ACTIVE INGREDIENT≠

LOW DOSE

**ASPIRIN REGIMEN** 

Aspirin 81 mg

PAIN RELIEVER (NSAID)

Safety Coated††

#### **TABLETS**

†Talk to your doctor or other healthcare provider before using this product for your heart. Aspirin is not right for everyone.

††Coating helps protect against stomach upset

≠This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Bayer® Low Dose Aspirin.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

**DISTRIBUTED BY** 

TOPCO ASSOCIATES LLC

**ELK GROVE VILLAGE, IL 60007** 

#### **Product Label**



### **TOPCARE HEALTH Low Dose Aspirin 81 mg**

titanium dioxide, triethyl citrate

D&C yellow #10, lactose

arthrits.

### LOW DOSE ASPIRIN

aspirin tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-980
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	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLACRILIN POTASSIUM (UNII: 0BZ5A00FQU)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
SOYBEAN (UNII: L7HT8F1ZOD)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Product Characteristics				
Color	yellow	Score	no score	
Shape	ROUND	Size	6mm	
Flavor		Imprint Code	P	
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:76162- 980-50	1 in 1 BOX	08/01/2023			
1		500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				
2	NDC:76162- 980-05	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2023			
3	NDC:76162- 980-12	1 in 1 BOX	08/01/2023			
3		120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	08/01/2023	

## Labeler - Topco Associates (006935977)

Revised: 6/2024 Topco Associates