ASPIRIN- aspirin tablet, coated TOP CARE (Topco Associates LLC)

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 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 have high blood pressure, heart disease, liver cirrhosis or kidney disease
- you have asthma
- you are taking a diuretic

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:
 - feel faint
 - have bloody or black stools
 - vomit blood
 - have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- fever gets 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 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: consult a doctor

Other information

store between 15-30°C (59-86°F)

Inactive ingredients

D&C yellow #10, FD&C yellow #6, methacrylic acid copolymer, microcrystalline cellulose, pregelatinized starch (corn), silicon dioxide, sodium bicarbonate, sodium lauryl sulfate, stearic acid, talc, 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 REGIMENT

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.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

topcare@topcare.com

Product Label



TOPCARE HEALTH Aspirin 81 mg

ASPIRIN

aspirin tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-968
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	
	SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
	TALC (UNII: 7SEV7J4R1U)		

TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics				
Color	yellow	Score	no score	
Shape	ROUND	Size	7mm	
Flavor		Imprint Code	E	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:36800- 968-12	1 in 1 BOX	04/01/2020		
1		120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
2	NDC:36800- 968-50	1 in 1 CARTON	04/01/2020		
2		500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
3	NDC:36800- 968-05	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M013	04/01/2020		

Labeler - TOP CARE (Topco Associates LLC) (006935977)

Revised: 6/2024 TOP CARE (Topco Associates LLC)