ASPIRIN LOW DOSE ENTERIC COATED- aspirin tablet, coated
A-S Medication Solutions

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.

Active Ingredient in Each tablet

Aspirin 81 mg (NSAID) Non-steroidal anti-inflammatory drug

Ask a doctor before use if: stomach bleeding waring 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, hou have lost a lot of fluid due to vomiting or diarhea

Uses: temporarily relieves minor aches and pains: for other uses, see your doctor, but do not use for more than 10 days without consulting your doctor because serious side effects may occur.

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 reactino which may include: hives, facial swelling, shock, asthma(wheezingStomach bleeding warning: This product contains an NSAID which may cause severe stomach bleeding. The chance is higher if you: are age 60 or older, hae had stomach ulcers or bleeding problems, take a blood thinning (anticoagulant) or steroid drug, take other drugs containing prescription or non prescription 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.

Ask a doctor or pharmacist before use if you are taking a prescription drug for diabetes, gout, or arthritis; under a doctor's care for any serious condition; taking any other drug

Do not use if your are allergic to aspirin or any other pain relieiver/fever reducer

Stop use and ask a doctor 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 more than 10 days, fever gets worse or lasts more than 3 days, redness or swelling is present in the painful area, any new symptoms appear

If pregnant or breast-feeding, ask a health profession 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 the 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 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

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, talc, itianium dioxide

Uses - temporarily relieves minor aches and pains for other uses, see your doctor, but do not use for more than 10 days without consulting your doctor because serious side effects may occur

HOW SUPPLIED

Product: 50090-2832

NDC: 50090-2832-0 1 TABLET, COATED in a BLISTER PACK / 33 in a BOX, UNIT-DOSE

aspirin

ASPIRIN LOW DOSE ENTERIC COATED

aspirin tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50090-2832(NDC:49483-387)
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**
anhydrous lactose (UNII: 3SY5LH9PMK)	
carnauba wax (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
croscarmellose sodium (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
IRON (UNII: E1UOL152H7)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
triethyl citrate (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	yellow	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	embossed;upper;heart;lower;plain
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-2832-0	33 in 1 BOX, UNIT-DOSE	02/01/2017	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	06/28/2010	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-2832)

Revised: 9/2018 A-S Medication Solutions