

ASPIRIN LOW DOSE- aspirin tablet
America Medic

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.

Drug facts

Aspirin

Internal Analgesic.

Keep out of reach of children. In case of overdose get medical help or contact a poison control center right away.

Oral Analgesic. Aspirin is not appropriate for everyone, so be sure to talk to a doctor before starting an Aspirin regimen.

Do not use this product if you are allergic to Aspirin or any other pain/fever product.

If pregnant or breastfeeding contact a doctor before using.

Contact a doctor or pharmacist if you are taking a prescription drug for-Gout, Diabetes or Arthritis.

Contact a doctor right away if: An allergic reaction occurs.

Drink a full glass of water with each dose.

Adults and children 12 years of age and up: Take 4-8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless indicated by a doctor.. Children under 12 years of age : Consult a Doctor.

Yellow # 10

Yellow # 6

Methacrylic Acid Copolymer

Microcrystalline Cellulose

Stearic Acid

Titanium Dioxide

Triethyl Citrate



Image of carton

ASPIRIN LOW DOSE

aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49638-001
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)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	yellow (yellow)	Score	no score
Shape	ROUND (tablet)	Size	6mm
Flavor		Imprint Code	C3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49638-001-02	1 in 1 CARTON		
1	NDC:49638-001-01	120 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	05/15/2012	

Labeler - America Medic (071065464)

Establishment

Name	Address	ID/FEI	Business Operations
America Medic		071065464	relabel, repack

Establishment			
Name	Address	ID/FEI	Business Operations
Cispharma Inc.		833171445	manufacture

Revised: 5/2012

America Medic