

ASPIRIN ENTERIC COATED- aspirin tablet, coated
Unit Dose Services

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.

ASPIRIN ENTERIC COATED

HOW SUPPLIED

Product: 50436-0127

NDC: 50436-0127-1 30 TABLET, COATED in a BOTTLE

ASPIR LOW (ASPIRIN) TABLET

NDC: 50436-0127-1

ASPIRIN
(ENTERIC COATED)
81 MG / 30 TAB

Active ingredient:
 (in each tablet)
 Aspirin 81mg (NSAID)

WARNING: KEEP OUT OF REACH OF CHILDREN
 STORE AT 20-25° C (68-77° F)
 ROOM TEMPERATURE. SEE PACKAGE
 INSERT FOR DOSAGE INFORMATION.



DIST. BY: MAJOR PHARMACEUTICALS
 LIVONIA, MI 48150 USA
 MFG NDC: 0904-7704-80
 MFG LOT: XXXXX
 LOT: XXXXX EXP: XX/XX/XX
 Pkg by: Unit Dose Services, LLC
 Dania, FL 33004 Rev. 1

NDC: 50436-0127-1
 DRUG: ASPIRIN
 (ENTERIC COATED) 81 MG / 30 TAB
 LOT: XXXXX EXP: XX/XX/XX

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ASPIRIN ENTERIC COATED

aspirin tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50436-0127(NDC:49483-481)
Route of Administration	ORAL	DEA Schedule	CIV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	HEART
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50436-0127-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	06/19/2015	

Labeler - Unit Dose Services (831995316)

Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Services		831995316	REPACK(50436-0127) , RELABEL(50436-0127)