

ASPIRIN- aspirin tablet, coated
Cardinal Health

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 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, you have not been drinking fluids, you have lost a lot of fluid due to vomiting or diarrhea

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 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 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 reliever/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, titanium 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

SKY

Manufactured By: Time-Cap Labs

7 Michael Ave.

Farmingdale, NY 11735

Distributed By McKesson Packaging Services

a business unit of McKesson Corporation

7101 Weddington Road

Concord, NC 28027

Validated with McKesson's PROmanager-Rx

Automated storage & dispensing system

for Package-Ready Oral solids

www.PROmanager-Rx.com

Repackaged by:

Cardinal Health

Zanesville, OH 43701

L48271501116

Principal Display Panel

Aspirin DR Enteric Coated Tablets, USP

81 mg

10 Tablets



NDC 55154-1494-0

J84

**ASPIRIN DR ENTERIC COATED
TABLETS, USP 81mg**

10 TABLETS

Active ingredient (in each tablet)

Aspirin 81 mg (NSAID*)

Purpose

Pain reliever

*nonsteroidal anti-inflammatory drug

Uses Temporarily relieves minor aches and pains or as recommended by your doctor

Do not use if you are allergic to aspirin or any other pain reliever/fever reducer

Allergy alert: Aspirin may cause a severe allergic reaction which may include: - hives - facial swelling - shock - asthma (wheezing)

For Directions and Warnings: See product insert for prescribing information, precautions and warnings.

STORAGE: Store at 25 C (77 F) excursions permitted between 15 - 30 C (59 - 86 F)

Consult a physician before the use of this product.

WARNING: This Unit Dose package is not child resistant and is intended for Institutional Use Only.

Keep this and all drugs out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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Repackaged by Cardinal Health

Zanesville, OH 43701

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LOT #: XXXX



EXP. DATE: 12/34

ASPIRIN

aspirin tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55154-1494(NDC:63739-522)
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: 3S5Y5LH9PMK)	
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)	
CELLULOSE, MICROCRYSTALLINE (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:55154-1494-0	10 in 1 BAG	11/13/2012	
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	11/13/2012	

Labeler - Cardinal Health (188557102)

Establishment

Name	Address	ID/FEI	Business Operations
Cardinal Health		188557102	REPACK(55154-1494)

