

**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.*

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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 you're 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

## 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 - 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

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, triethyl citrate

STORAGE: Store at 25 C (77 F) excursions permitted between 15 - 30 C (59 - 86 F) - use by expiration date on package

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.

**WARNING:** This package is intended for institutional use only. 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 the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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

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Repackaged by Cardinal Health  
Zanesville, OH 43701  
L4827150-10614

Repackaged by Cardinal Health  
Zanesville, OH 43701  
L4827150-20614

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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

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

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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

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 - ringing in the ears or a loss of hearing occurs

Validated with McKesson's PROmanager-Rx  
Automated storage & dispensing system  
for Package-Ready Oral solids  
[www.PROmanager-Rx.com](http://www.PROmanager-Rx.com)

LOT #: XXXX



EXP. DATE: 12/34



## ASPIRIN

aspirin tablet, coated

### Product Information

Product Type

HUMAN OTC DRUG  
LABEL

Item Code (Source)

NDC:55154-  
1494(NDC:63739-522)

Route of Administration

ORAL

DEA Schedule

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
aspirin (aspirin)	aspirin	81 mg

**Inactive Ingredients**

Ingredient Name	Strength
anhydrous lactose	
carnauba wax	
SILICON DIOXIDE	
croscarmellose sodium	
D&C YELLOW NO. 10	
IRON	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A	
CELLULOSE, MICROCRYSTALLINE	
DIMETHICONE	
POLYSORBATE 80	
SODIUM HYDROXIDE	
SODIUM LAURYL SULFATE	
TALC	
TITANIUM DIOXIDE	
triethyl citrate	

**Product Characteristics**

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55154-1494-0	10 in 1 BAG		
1		1 in 1 BLISTER PACK		

**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
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Revised: 6/2014

Cardinal Health