ASPIRIN ENTERIC COATED- aspirin tablet, delayed release
Chain Drug Consortium, LLC

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

Active ingredient (in each tablet)

Aspirin 81 mg (NSAID)*

*nonsteroidal anti- inflammatory drug

Purpose

Pain reliever

Uses

- temporarily relieves minor aches and pains
- other therapy as recommended by your doctor. **Because of its delayed action, this product will not provide fast relief of headaches, fever, or other symptoms needing immediate relief.**

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.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma(wheezing)
- shock

Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause 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 nonprescription 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

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer

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

Ask a doctor or pharmacist before use if you are

taking a prescription drug for:
- anticoagulation (thinning of the blood)
- gout
- diabetes
- arthritis

Stop use and ask a doctor if
- you experience any of the following signs of stomach bleeding:
- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- allergic reaction occurs
- ringing in the ears or a loss of hearing occurs
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- any new symptoms appear
- redness or swelling is present in the painful area

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 reach of children

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions
- **do not exceed recommended dosage**
- drink a full glass of water with each dose
- adults and children 12 years of age 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 of age: consult a doctor

Other information
- store at controlled room temperature 15°-30°C (59°-86°F)
- do not use if imprinted safety seal under cap is broken or missing

Inactive ingredients

*acetylated monoglycerides, *anhydrous lactose, *carnauba wax, colloidal silicon dioxide,*corn starch, *croscarmellose sodium, D&C Yellow #10 Aluminum Lake, FD&C Yellow #6 Aluminum Lake, hypromellose, *hypromellose phthalate, *iron oxide Yellow (iron oxide ochre), methacrylic acid copolymer, microcrystalline cellulose, *mineral oil, *polyethylene

glycol (PEG)-400, *polysorbate 80, povidone, pregelatinized starch, *propylene glycol, *simethicone, silicon dioxide, sodium bicarbonate, sodium hydroxide, sodium lauryl sulfate, starch, stearic acid, talc, titanium dioxide, triacetin, and triethyl citrate. *May also contain.

Questions or comments?

call toll free 1-877-753-3935

Principal Display Panel

†Compare to the active ingredient in Aspirin Regimen BAYER® 81 mg

SEE NEW WARNINGS INFORMATION

†Bayer® Aspirin is a trademark of Bayer Healthcare LLC (Morristown,NJ 07960). Bayer Healthcare LLC is not affiliated with The Kroger Co. or this product.

Enteric Coated Aspirin

adult low strength aspirin regimen**

Aspirin 81 mg

Pain reliever

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

**Ask your doctor before taking this product on a regular basis

DISTRIBUTED BY:

CHAIIN DRUG CONSORTIUM, LLC

3301 NW BOCA RATON BLVD SUITE 101

BOCA RATON, FL 33431

Product Label

ASPIRIN 81 MG

ASPIRIN ENTERIC COATED

aspirin tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-089
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
DIACETYLATED MONOGLYCERIDES (UNII: 5Z17386USF)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
HYPROMELLOSE PHTHALATE (24% PHTHALATE, 55 CST) (UNII: 87Y6436BKR)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONES (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics			
Color	YELLOW	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	E;HEART;81
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-089-03	1 in 1 CARTON		
1		120 in 1 BOTTLE; 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	03/22/2011	

Labeler - Chain Drug Consortium, LLC (101668460)

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