

**ENTERIC COATED ASPIRIN REGULAR STRENGTH- aspirin tablet, coated  
McKesson (Sunmark)**

*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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**Drug Facts**

**Active ingredient (in each tablet)**

**Aspirin 325 mg (NSAID)\***

**\*nonsteroidal anti-inflammatory drug**

**Purpose**

**Pain reliever**

**Uses**

- temporarily relieves minor aches and pains due to:
  - headache
  - toothache
  - colds
  - muscle pain
  - menstrual pain
  - minor arthritis pain
- or as recommended by a doctor

**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
- shock
- facial swelling
- 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 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 are allergic to aspirin or 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

- gout
- diabetes
- arthritis

**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
- an allergic reaction occurs. Seek medical help right away.
- new symptoms occur
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present

These could be signs of a serious condition.

**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**

- adults and children 12 years of age and over: take 1 to 2 tablets every 4 hours, while symptoms persist
- drink a full glass of water with each dose
- do not take more than 12 tablets in 24 hours unless directed by a doctor
- children under 12 years of age: do not use

**Other information**

- store at controlled room temperature 20°-25°C (68°-77°F)

**Inactive ingredients**

corn starch, croscarmellose sodium, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, mineral oil, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

**Questions or comments?**

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

**Principal Display Panel**

COMPARE TO ECOTRIN® ACTIVE INGREDIENT†

**Enteric Coated Aspirin**

Regular Strength

ASPIRIN REGIMEN\*\*

Pain reliever (NSAID)

PROTECTS AGAINST ASPIRIN STOMACH UPSET

GLUTEN FREE

325 mg EACH

†This product is not manufactured or distributed by Prestige Brands, Inc., distributor of Ecotrin®.

\*\*Talk to your doctor before starting an aspirin regimen.

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Please visit us at [www.sunmarkbrand.com](http://www.sunmarkbrand.com)

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS  
BROKEN OR MISSING.**

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

**Product label**

sunmark®

COMPARE TO ECOTRIN®  
ACTIVE INGREDIENT†  
NDC 49348-937-82

# enteric coated aspirin

Regular Strength

ASPIRIN REGIMEN\*\* Pain reliever (NSAID)

PROTECTS AGAINST ASPIRIN STOMACH UPSET

GLUTEN FREE



125 TABLETS, 325 mg EACH

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**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

## MEKESSON

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PLD-B135B FC002107

Lot No.:

Exp. Date:

# ENTERIC COATED ASPIRIN REGULAR STRENGTH

aspirin tablet, coated

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-937
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

## Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

## Product Characteristics

Color	ORANGE	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	T
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-937-82	1 in 1 BOX		
1		125 in 1 BOTTLE, PLASTIC		
2	NDC:49348-937-14	500 in 1 BOTTLE, PLASTIC		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part343	09/15/2010	

**Labeler** - McKesson (Sunmark) (177667227)

Revised: 6/2014

McKesson (Sunmark)