## ENTERIC COATED ASPIRIN REGULAR STRENGTH- aspirin tablet, coated Good Sense (Geiss, Destin & Dunn, Inc.)

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 active ingredient in Ecotrin®

## **Regular Strength**

Enteric

Aspirin

Safety Coated

Pain Reliever (NSAID)

## Aspirin Regimen\*\*

125 Tablets (325 mg Each)

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

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

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

Distributed by: Geiss, Destin & Dunn, Inc.

Peachtree City, GA 30269

www.valuelabels.com

## **Product label**



## ENTERIC COATED ASPIRIN REGULAR STRENGTH

aspirin tablet, coated

<b>Product Inform</b>	ation					
	ation					
Product T ype		HUMAN OTC DRUG Item Code (Source)		(Source)	NDC:50804-370	
Route of Administ	ration	ORAL				
Active Ingredie	nt/Active Moi	ety				
Ingredient Name		dient Name		Basis of Stre	ength Strength	
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E				ASPIRIN	3	325 mg
Inactive Ingred	ients					
		Ingredient Na	me			Strengtl
STARCH, CORN (UN	NII: 08232NY3SJ)					Ū
CROSCARMELLOS	E SODIUM (UNII:	M28OL1HH48)				
D&C YELLOW NO.						
FD&C YELLOW NO	<b>.6</b> (UNII: H77VEI9	J3A8)				
HYPRO MELLO SES	(UNII: 3NXW29V3	WO)				
METHACRYLIC AC	ID - METHYL MET	THACRYLATE COPOLYN	<b>MER (1:1)</b> (UNII: 74	G4R6TH13)		
CELLULOSE, MICR	OCRYSTALLINE	(UNII: OP1R32D61U)				
MINERAL OIL (UNI	l: T5L8T28FGP)					
POLYSORBATE 80	(UNII: 6OZP39ZG	8 H)				
DIMETHICO NE (UN	II: 92RU3N3Y1O)					
SO DIUM HYDRO XII	<b>DE</b> (UNII: 55X04Q	C32I)				
SODIUM LAURYL S	ULFATE (UNII: 36	58GB5141J)				
TALC (UNII: 7SEV7J	4R1U)					
TITANIUM DIO XIDI	E (UNII: 15FIX9V2J	P)				
TRIETHYL CITRAT	E (UNII: 8Z96QXE	06 UM)				
Product Charac						
Color		ORANGE Score			no score	
Shape	ROUNE			11mm		
Flavor		Imp	Imprint Code		Т	
Contains						
Packaging						
# Item Code	Package Description			Marketing Start Date	t Marketing End Date	
	1 in 1 BOX			0.0 /00 /00 44		
1 NDC:50804-370- 12		, PLASTIC; Type 0: Not a C		08/22/2011		

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC MONOGRAPH FINAL	part343	08/22/2011					
1							

Labeler - Good Sense (Geiss, Destin & Dunn, Inc.) (076059836)

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