# ECOTRIN- aspirin tablet, coated GlaxoSmithKline Consumer Healthcare LP

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) (Low Strength)

Aspirin (NSAID)\* 81mg

\*nonsteroidal anti-inflammatory drug

## Active ingredient (in each tablet) (Regular Strength)

Aspirin (NSAID)\* 325mg

\*nonsteroidal anti-inflammatory drug

#### Purpose

Pain reliever

#### Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - menstrual pain
  - innor arthritis pain
  - muscle pain
  - toothache
  - olds.
- 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
- 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 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 aspirin or any other pain reliever/fever reducer

#### Ask a doctor before use if

- stomach bleeding warnings 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 diabetes, gout, or arthritis

#### Stop use and ask a doctor if

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

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 (Low Strength)**

• adults and children 12 years of age or over: take 4 to 8 tablets every 4 hours, while symptoms persist. Drink a full glass of water with each dose.

- do not take more than 48 tablets in 24 hours unless directed by a doctor
- children under 12 years of age: ask a doctor

#### **Directions (Regular Strength)**

- adults and children 12 years of age or 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: ask a doctor

#### Other information

- Tamper Evident Feature: Do not use if printed inner-seal beneath cap is missing or broken.
- store below 25°C (77°F)

## **Inactive ingredients (Low Strength)**

carnauba wax, colloidal silicon dioxide, EDTA, FD&C yellow#6, glyceryl monostearate, hypromellose, methacrylic acid copolymer, methylparaben, microcrystalline cellulose, polysorbate 80, propylparaben, starch, stearic acid, talc, titanium dioxide, triethyl citrate. Printed with edible black ink.

#### **Inactive ingredients (Regular Strength)**

carnauba wax, colloidal silicon dioxide, EDTA, FD&C yellow#6, glyceryl monostearate, hypromellose, methacrylic acid copolymer, methylparaben, microcrystalline cellulose, polysorbate 80, pregelatinized starch, propylparaben, sodium starch glycolate, stearic acid, talc, titanium dioxide, triethyl citrate. Printed with edible ink.

#### Questions or comments?

call toll-free 1-800-245-1040 (English/Spanish) weekdays

ECOTRIN is a registered trademark of the GlaxoSmithKline group of companies.

GlaxoSmithKline Consumer Healthcare, L.P.

Moon Township, PA 15108, Made in Thailand

www.ecotrin.com

### **Principal Display Panel (Low Strength)**

NDC 0135-0117-88

 $Ecotrin^{ ext{ in}}$ 

Safety Coated Aspirin (NSAID)Pain Reliever

The Aspirin Regimen That's Smart For Your Heart

#1 CARDIOLOGIST Recommended Aspirin

81mg Low Strength

365 Tablets

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN.

#### **VALUE SIZE!**

©2011 GlaxoSmithKline 100183XB



**Principal Display Panel (Regular Strength)** 

NDC 0135-0014-30

Ecotrin<sup>®</sup>

Safety Coated Aspirin (NSAID)Pain Reliever

The Aspirin Regimen That's Smart For Your Heart

#1 CARDIOLOGIST Recommended Aspirin

325mg Regular Strength

300 Tablets

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN.

**VALUE SIZE!** 

©2011 GlaxoSmithKline

100198XB



## **ECOTRIN**

aspirin tablet, coated

### **Product Information**

Product Type HUMAN OTC DRUG LABEL Item Code (Source) NDC:0135-0117

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		
CARNAUBA WAX			
SILICON DIO XIDE			
EDETIC ACID			
FD&C YELLOW NO. 6			
GLYCERYL MONOSTEARATE			
HYPROMELLOSES			
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A			
METHYLPARABEN			
CELLULO SE, MICRO CRYSTALLINE			
POLYSORBATE 80			
PROPYLPARABEN			
STEARIC ACID			
TALC			
TITANIUM DIO XIDE			
TRIETHYL CITRATE			

Product Characteristics					
Color	ORANGE	Score	no score		
Shape	ROUND	Size	8 mm		
Flavor		Imprint Code	Ecotrin;Low		
Contains					

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0135-0117-88	365 in 1 BOTTLE			
2	NDC:0135-0117-02	45 in 1 BOTTLE			
3	NDC:0135-0117-01	150 in 1 BOTTLE			
4	NDC:0135-0117-87	1 in 1 CARTON			
4		14 in 1 BOTTLE			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part343	11/12/2010	07/31/2014	

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aspirin tablet, coated

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Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
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ASPIRIN (ASPIRIN)	ASPIRIN	325 mg	

Inactive Ingredients	
Ingredient Name	Strength
CARNAUBA WAX	
SILICON DIO XIDE	
EDETIC ACID	
FD&C YELLOW NO. 6	
GLYCERYL MONOSTEARATE	
HYPROMELLOSES	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A	
METHYLPARABEN	
CELLULO SE, MICRO CRYSTALLINE	

POLYSORBATE 80	
PROPYLPARABEN	
STARCH, CORN	
STEARIC ACID	
TALC	
TITANIUM DIO XIDE	
TRIETHYL CITRATE	

Product Characteristics				
Color	ORANGE	Score	no score	
Shape	ROUND	Size	10 mm	
Flavor		Imprint Code	Ecotrin;Reg	
Contains				

]	Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0135-0014-27	125 in 1 BOTTLE			
2	NDC:0135-0014-30	300 in 1 BOTTLE			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part343	11/12/20 10	06/30/2014	

## Labeler - GlaxoSmithKline Consumer Healthcare LP (828924212)

Revised: 3/2013 GlaxoSmithKline Consumer Healthcare LP