

ECOTRIN- aspirin tablet, coated
Medtech Products 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.

Ecotrin Low Strength

Drug Facts

Active ingredient

(in each tablet)

Aspirin (NSAID) *81mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - minor arthritis pain
 - toothache
 - menstrual pain
 - colds

- 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 have ever had an allergic reaction 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 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

- adults and children 12 years of age and 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

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

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 ink.

Questions or comments?

call toll-free **1-866-255-5202** (English/Spanish) weekdays

PRINCIPAL DISPLAY PANEL

The Aspirin Regimen That's Smart For Your Heart

Ecotrin[®]

Safety Coated Aspirin (NSAID) Pain Reliever

#1 CARDIOLOGIST Recommended Aspirin

81 mg Low Strength

150 Tablets



ECOTRIN

aspirin tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63029-301
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
EDETIC ACID (UNII: 9G34HU7RV0)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029-301-07	1 in 1 BOX		
1		7 in 1 BLISTER PACK		
2	NDC:63029-301-08	1 in 1 CARTON		
2		8 in 1 BLISTER PACK		
3	NDC:63029-301-01	1 in 1 BOX		
3		150 in 1 BOTTLE, PLASTIC		
4	NDC:63029-301-14	1 in 1 CARTON		
4		14 in 1 BOTTLE, PLASTIC		
5	NDC:63029-301-45	45 in 1 BOTTLE, PLASTIC		
6	NDC:63029-301-65	365 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part343	06/01/2012	

Labeler - Medtech Products Inc. (122715688)

