

**ECOTRIN REGULAR STRENGTH- 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.*

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**Ecotrin Regular**

***Drug Facts***

***Active ingredient***

***(in each tablet)***

Aspirin (NSAID\*) 325mg

\*nonsteroidal anti-inflammatory drug

***Purpose***

Pain reliever

***Uses***

- temporarily relieves minor aches and pains due to:
  - minor arthritis pain
  - headache
  - toothache
  - menstrual pain
  - muscle 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
- 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 (1-800-222-1222) right away.

### **Directions**

- drink a full glass of water with each dose
- **adults and children 12 years of age and over:** take 1 to 2 tablets every 4 hours while symptoms last
  - 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**

- store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)

- see end flap for expiration date and lot number

### ***Inactive ingredients***

black iron oxide, cellulose, colloidal silicon dioxide, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, polydextrose, polyethylene glycol, polyvinyl acetate phthalate, propylene glycol, shellac wax, simethicone, sodium alginate, sodium bicarbonate, stearic acid, talc, titanium dioxide, triacetin, triethyl citrate

### ***Questions?***

**1-800-255-5202** Ecotrin.com

### **PRINCIPAL DISPLAY PANEL**

**Ecotrin®**

Safety Coated Aspirin  
(NSAID) Pain Reliever  
325 mg Regular Strength

125 Tablets



**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength | Strength |
|--|-------------------|----------|
| ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN           | 325 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)  |          |
| METHYL PARABEN (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)   |          |
| PROPYL PARABEN (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         | 10mm         |
| Flavor   |        | Imprint Code | Eco trin;Reg |
| Contains |        |              |              |

**Packaging**

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:63029-302-01 | 1 in 1 CARTON   | 06/01/2012           |                    |
| 1 |                  | 300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:63029-302-02 | 1 in 1 BOX  | 06/01/2012           |                    |
| 2 |                  | 125 in 1 BOTTLE, PLASTIC; 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                                  | 06/01/2012           |                    |

