

**ASPIRIN EC- aspirin tablet, coated**  
**Physicians Total Care, 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) (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
  - minor arthritis pain
  - muscle pain
  - toothache
  - 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
- 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](http://www.ecotrin.com)

Additional barcode labeling by:  
Physicians Total Care, Inc.  
Tulsa, Oklahoma 74146

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

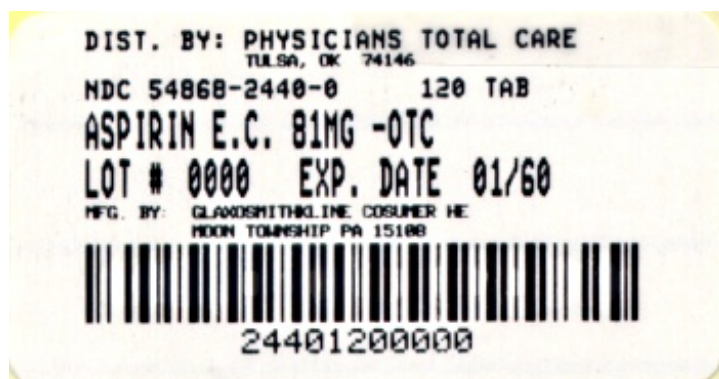
NDC 54868-2440-0

**Safety Coated Aspirin (NSAID) Pain Reliever**

**The Aspirin Regimen That's Smart For Your Heart**

**#1 CARDIOLOGIST Recommended Aspirin**

**81mg Low Strength**



THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN.

NDC 54868-2405-3

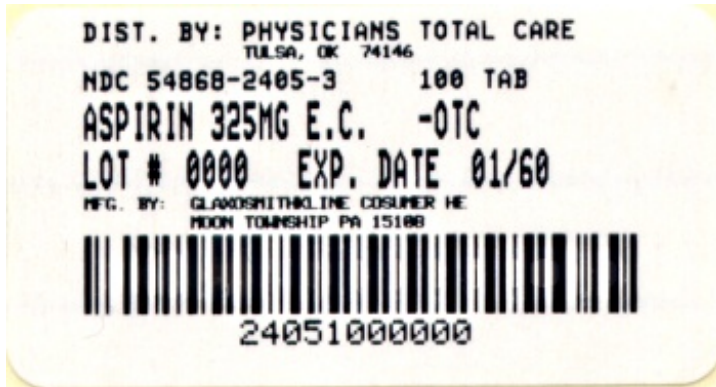
**Safety Coated Aspirin (NSAID) Pain Reliever**

**The Aspirin Regimen That's Smart For Your Heart**

**#1 CARDIOLOGIST Recommended Aspirin**

**325mg Regular Strength**

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN.



## ASPIRIN EC

aspirin tablet, coated

### Product Information

|                         |                |                    |                                |
|-------------------------|----------------|--------------------|--------------------------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:54868-2440 (NDC:0135-0117) |
| 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)  |          |
| METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J) |          |
| METHYL PARABEN (UNII: A2I8C7HI9T)   |          |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)                              |          |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H)   |          |
| PROPYL PARABEN (UNII: Z8IX2SC1OH)   |          |

|  |  |
|--|--|
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)     |  |
| <b>TALC</b> (UNII: 7SEV7J4R1U)             |  |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) |  |
| <b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM) |  |

### Product Characteristics

|                 |        |                     |             |
|-----------------|--------|---------------------|-------------|
| <b>Color</b>    | ORANGE | <b>Score</b>        | no score    |
| <b>Shape</b>    | ROUND  | <b>Size</b>         | 8mm         |
| <b>Flavor</b>   |        | <b>Imprint Code</b> | Ecotrin;Low |
| <b>Contains</b> |        |                     |             |

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:54868-2440-0 | 120 in 1 BOTTLE     |                      |                    |
| 2 | NDC:54868-2440-1 | 36 in 1 BOTTLE      |                      |                    |
| 3 | NDC:54868-2440-2 | 1000 in 1 BOTTLE    |                      |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part343                                  | 11/30/2000           |                    |

## ASPIRIN EC

aspirin tablet, coated

### Product Information

|                                |                |                           |                               |
|--------------------------------|----------------|---------------------------|-------------------------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:54868-2405(NDC:0135-0014) |
| <b>Route of Administration</b> | 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 |
|--|----------|
| 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)         |          |

|   |  |
|---|--|
| METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J) |  |
| METHYL PARABEN (UNII: A2I8C7HI9T)   |  |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)                              |  |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H)   |  |
| PROPYL PARABEN (UNII: Z8IX2SC1OH)   |  |
| STARCH, CORN (UNII: O8232NY3SJ)   |  |
| 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         | 10 mm       |
| Flavor   |        | Imprint Code | Ecotrin;Reg |
| Contains |        |              |             |

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:54868-2405-3 | 100 in 1 BOTTLE     |                      |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part343                                  | 09/10/1993           |                    |

**Labeler** - Physicians Total Care, Inc. (194123980)

### Establishment

| Name                        | Address | ID/FEI    | Business Operations |
|-----------------------------|---------|-----------|---------------------|
| Physicians Total Care, Inc. |         | 194123980 | relabel             |