**ASPIRIN ENTERIC SAFETY COATED- aspirin tablet, delayed release**
**Care One (American Sales Company)**

*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 81 mg (NSAID)***

*nonsteroidal anti- inflammatory drug

**Purpose**

**Pain reliever**

**Uses**

- temporarily relieves minor aches and pains
- other therapy as recommended by your doctor. **Because of its delayed action, this product will not provide fast relief of headaches, fever, or other symptoms needing immediate relief.**

**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
- asthma(wheezing)
- shock

**Stomach bleeding warning**: This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause 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 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:
- anticoagulation (thinning of the blood)
- gout
- diabetes
- arthritis

**Stop use and ask a doctor if**
- 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
  - allergic reaction occurs
  - ringing in the ears or a loss of hearing occurs
  - pain gets worse or lasts more than 10 days
  - fever gets worse or lasts more than 3 days
  - any new symptoms appear
  - redness or swelling is present in the painful area

**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**
- **do not exceed recommended dosage**
- drink a full glass of water with each dose
- adults and children 12 years of age and over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours, unless directed by a doctor
- children under 12 years of age: consult a doctor

**Other information**
- store at controlled room temperature 15°-30°C (59°-86°F)
- do not use if imprinted safety seal under cap is broken or missing
- †This product is not manufactured or distributed by Bayer Corporation Consumer Care Division, owner of the registered trademark Aspirin Regimen Bayer® 81 mg

**Inactive ingredients**

*acetylated monoglycerides, *anhydrous lactose, *carnauba wax, colloidal silicon dioxide,*corn

starch, *croscarmellose sodium, D&C Yellow #10 Aluminum Lake, FD&C Yellow #6 Aluminum Lake, hypromellose, *hypromellose phthalate, *iron oxide Yellow (iron oxide ochre), methacrylic acid copolymer, microcrystalline cellulose, *mineral oil, *polyethylene glycol (PEG)-400, *polysorbate 80, povidone, pregelatinized starch, *propylene glycol, *simethicone, silicon dioxide, sodium bicarbonate, sodium hydroxide, sodium lauryl sulfate, starch, stearic acid, talc, titanium dioxide, triacitin, and triethyl citrate. *May also contain.

**Principal Display Panel**

Compare to the active ingredient in Aspirin Regimen Bayer® 81 mg †

**SEE NEW WARNINGS INFORMATION**

Enteric safety Coated/ Aspirin regimen**

**Ask your doctor before taking this product on a regular basis

Aspirin 81 mg

adult low strength

Pain reliever (NSAID)*

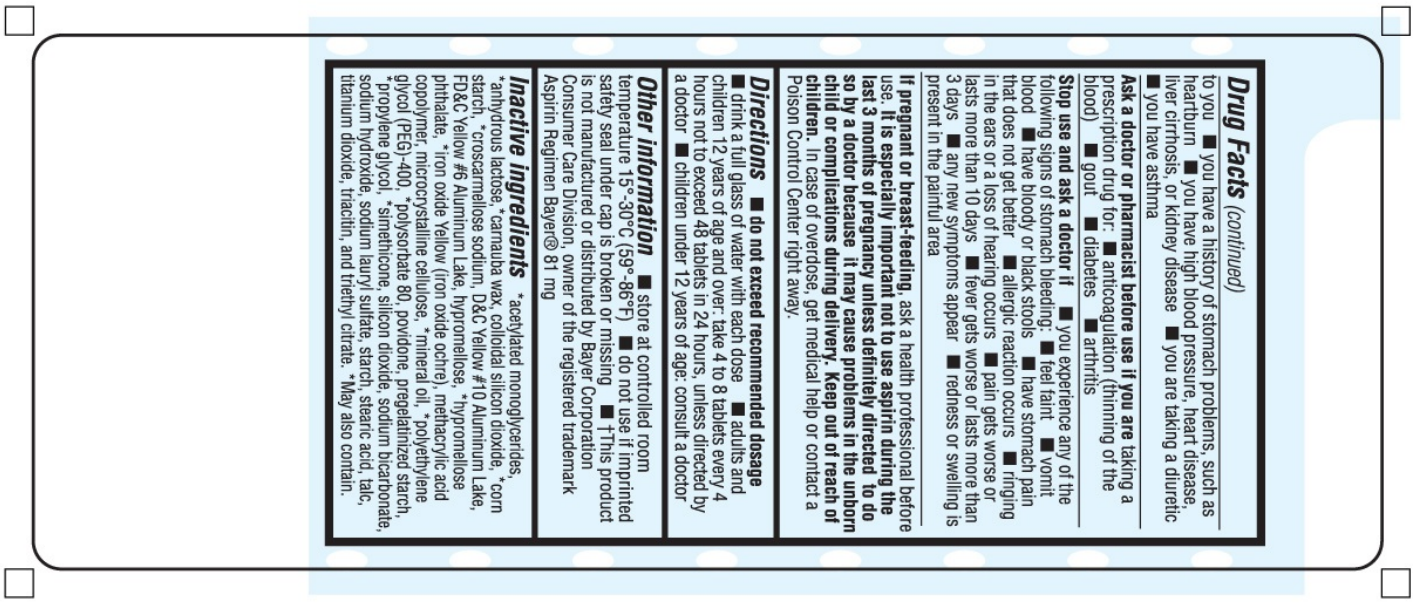
Low Dose

Distributed by: American sales company

4201 Walden avenue, Lancaster, NY 14086

www.care1.info

**Product Label**



Drug Facts (continued)

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: ■ anticoagulation (thinning of the blood) ■ gout ■ diabetes ■ arthritis

**Stop use and ask a doctor if** ■ 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 ■ allergic reaction occurs ■ ringing in the ears or a loss of hearing occurs ■ pain gets worse or lasts more than 10 days ■ fever gets worse or lasts more than 3 days ■ any new symptoms appear ■ redness or swelling is present in the painful area

**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** ■ **do not exceed recommended dosage** ■ drink a full glass of water with each dose ■ adults and children 12 years of age and over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours, unless directed by a doctor ■ children under 12 years of age: consult a doctor

**Other information** ■ store at controlled room temperature 15°-30°C (59°-86°F) ■ do not use if imprinted safety seal under cap is broken or missing ■ †This product is not manufactured or distributed by Bayer Corporation Consumer Care Division, owner of the registered trademark Aspirin Regimen Bayer® 81 mg

**Inactive ingredients** *acetylated monoglycerides, *anhydrous lactose, *carnauba wax, colloidal silicon dioxide, *corn starch, *croscarmellose sodium, D&C Yellow #10 Aluminum Lake, FD&C Yellow #6 Aluminum Lake, hypromellose, *hypromellose phthalate, *iron oxide Yellow (iron oxide ochre), methacrylic acid copolymer, microcrystalline cellulose, *mineral oil, *polyethylene glycol (PEG)-400, *polysorbate 80, povidone, pregelatinized starch, *propylene glycol, *simethicone, silicon dioxide, sodium bicarbonate, sodium hydroxide, sodium lauryl sulfate, starch, stearic acid, talc, titanium dioxide, triacitin, and triethyl citrate. *May also contain.

**Aspirin 81 mg**

# ASPIRIN ENTERIC SAFETY COATED

aspirin tablet, delayed release

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:41520-440 |
| **Route of Administration** | ORAL | **DEA Schedule** | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **ASPIRIN** (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN | 81 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **DIACETYLATED MONOGLYCERIDES** (UNII: 5Z17386USF) | |
| **ANHYDROUS LACTOSE** (UNII: 3SY5LH9PMK) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **D&C YELLOW NO. 10** (UNII: 35SW5USQ3G) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **HYPROMELLOSE PHTHALATE (24% PHTHALATE, 55 CST)** (UNII: 87Y6436BKR) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |
| **METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1)** (UNII: 74G4R6TH13) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **MINERAL OIL** (UNII: T5L8T28FGP) | |
| **POLYETHYLENE GLYCOL 400** (UNII: B697894SGQ) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **POVIDONES** (UNII: FZ989GH94E) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **DIMETHICONE** (UNII: 92RU3N3Y1O) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **SODIUM BICARBONATE** (UNII: 8MDF5V39QO) | |
| **SODIUM HYDROXIDE** (UNII: 55X04QC32I) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **TRIACETIN** (UNII: XHX3C3X673) | |
| **TRIETHYL CITRATE** (UNII: 8Z96QXD6UM) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | YELLOW | **Score** | no score |
| **Shape** | ROUND | **Size** | 10mm |
| **Flavor** | | **Imprint Code** | E;HEART;81 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:41520-440-14 | 1 in 1 BOX | | |
| **1** | | 144 in 1 BOTTLE | | |
| **2** | NDC:41520-440-30 | 1 in 1 BOX | | |
| **2** | | 300 in 1 BOTTLE | | |
| **3** | NDC:41520-440-12 | 1 in 1 BOX | | |

| | | | | |
|---|---|---|---|---|
| **3** | | 120 in 1 BOTTLE | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part343 | 07/15/2010 | |

## Labeler - Care One (American Sales Company) (809183973)

## Registrant - P and L Development of New York Corporation (800014821)

Revised: 12/2012 Care One (American Sales Company)