

**SAFETY COATED ASPIRIN- aspirin tablet**  
**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
- for other uses, see your doctor, but do not use for more than 10 days without consulting your doctor because serious side effects may occur

**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:

- facial swelling
- hives
- asthma (wheezing)
- shock

**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 are allergic 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:

- 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 specifically directed to do so by a doctor because it may cause problems in the unborn child or complications during the delivery.**

### **Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away.

### **Directions**

- drink a full glass of water with each dose
- **adults and children 12 years 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:** do not use unless directed by 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 McNeil Consumer & Speciality Pharmaceuticals, owner of the registered trademark ST. JOSEPH® 81 mg

### **Inactive ingredients**

anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, FD&C Red # 40 Aluminum lake, FD&C Yellow # 6 Aluminum Lake, iron oxide ochre, methacrylic acid copolymer, microcrystalline cellulose, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, triethyl citrate

**Principal Display Panel**

Compare to the active ingredient in St. Joseph® Aspirin †

Adult Low Strength

Aspirin Regimen\*\*

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

SAFETY COATED ASPIRIN

protects against stomach upset

pain reliever (NSAID\*)

**See New Warnings Information**

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION**

Distributed by: American Sales Company

4201 walden avenue, Lancaster, NY 14086

[www.care1.com](http://www.care1.com)

**Product Label**

02456023

V51e

**Drug Facts** (continued)

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 are allergic 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: ■ 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

DISTRIBUTED BY: American Sales Company  
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www.care1inc.com

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PLD-E  
F10C0180  
Lot No.:

Exp. Date:

KEEP OUTER CARTON FOR COMPLETE  
WARNINGS AND PRODUCT INFORMATION

**Drug Facts**

**Active ingredient (in each tablet)**  
Aspirin 81 mg (NSAID)\* Pain reliever

**Uses** ■ Temporarily relieves minor aches and pains ■ for other uses, see your doctor, but do not use for more than 10 days without consulting your doctor because serious side effects may occur

**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: ■ facial swelling ■ hives ■ asthma (wheezing) ■ shock

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe

**Drug Facts** (continued)

sodium, FD&C Red # 40 Aluminum Lake, FD&C Yellow # 6 Aluminum Lake, iron oxide ochre, methacrylic acid copolymer, microcrystalline cellulose, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, triethyl citrate

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

Compare to the active ingredient in St. Joseph<sup>®</sup> Aspirin



**Drug Facts** (continued)

**Directions** ■ drink a full glass of water with each dose ■ adults and children 12 years 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: do not use unless directed by 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 McNeil Consumer & Specialty Pharmaceuticals, owner of the registered trademark ST. JOSEPH<sup>®</sup> 81 mg

**Inactive ingredients** anhydrous lactose, carnuba wax, colloidal silicon dioxide, croscarmellose

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**NOT TO USE ASPIRIN DURING THE LAST 3 MONTHS OF PREGNANCY UNLESS SPECIFICALLY DIRECTED TO DO SO BY A DOCTOR BECAUSE IT MAY CAUSE PROBLEMS IN THE UNBORN CHILD OR COMPLICATIONS DURING THE DELIVERY.**

KEEP OUTER CARTON FOR COMPLETE  
WARNINGS AND PRODUCT INFORMATION

**Aspirin 81 mg Enteric Coated**

**SAFETY COATED ASPIRIN**

aspirin tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41520-103
<b>Route of Administration</b>	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
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

## Product Characteristics

Color	ORANGE (peach)	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	heart;328
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-103-18	1 in 1 BOX		
1		180 in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	07/30/2010	

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

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