ASPIRIN REGULAR STRENGTH- aspirin tablet, coated
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.

DRUG FACTS

Active ingredient (in each tablet)

Aspirin 325 mg (NSAID)*

*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 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 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

- store at controlled room temperature 15º- 30º C (59º- 86º F)
- do not use if imprinted safety seal under cap is broken or missing
- †This product is not manufactured or distributed by Glaxosmithkline, owner of the registered trademark Ecotrin®

Inactive ingredients

corn starch, croscarmellose sodium, D&C Yellow #10 Aluminum Lake, FD&C Yellow #6 Aluminum Lake, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, mineral oil, polysorbate

80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

PRINCIPAL DISPLAY PANEL

COMPARE TO THE ACTIVE INGREDIENT IN ECOTRIN® †

Aspirin Regimen**

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

ASPIRIN

325 mg Regular strength

Pain reliever (NSAID)*

SEE NEW WARNINGS INFORMATION

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Product label

Aspirin 325 mg

ASPIRIN REGULAR STRENGTH

aspirin tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:41520-370
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

ASPIRIN (ASPIRIN)	ASPIRIN	325 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN	
CROSCARMELLOSE SODIUM	
D&C YELLOW NO. 10	
FD&C YELLOW NO. 6	
HYPROMELLOSES	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1)	
CELLULOSE, MICROCRYSTALLINE	
MINERAL OIL	
POLYSORBATE 80	
DIMETHICONE	
SODIUM HYDROXIDE	
SODIUM LAURYL SULFATE	
TALC	
TITANIUM DIOXIDE	
TRIETHYL CITRATE	
ALUMINUM OXIDE	

Product Characteristics

Color	ORANGE	**Score**	no score
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	T
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-370-12	1 in 1 BOX		
1		125 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part343	08/02/2011	

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

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

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