

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
 - muscle pain
 - toothache
 - menstrual pain\colds
 - minor arthritis pain
- 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 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
 - have bloody or black stools
 - vomit blood
 - have stomach pain that does not get better
- an allergic reaction occurs. Seek medical help right away.
- new symptoms occur
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present

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: do not use

Other information

- store at controlled room temperature 20°-25°C (68°-77°F)

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**

325 mg Regular Strength

ASPIRIN

Pain reliever (NSAID)

Enteric Safety Coated

Tablets

†This product is not manufactured or distributed by Prestige Brands, inc., distributor of Ecotrin®.

**Talk to your doctor before starting aspirin regimen.

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS
BROKEN OR MISSING.**

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY FOODHOLD U.S.A., LLC

LANDOVER, MD 20785

1-877-846-9949

Product label



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Drug Facts (continued)

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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, poly sorbate 80, smecticon, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

This product is not manufactured or distributed by Prestige Brands, Inc., distributor of Ecotrin®.

Talk to your doctor before starting or resuming aspirin regimen.

TAMPER EVIDENCE DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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PLD-B135B FC002099

Lot No.:
Exp. Date:



Care One Aspirin Tablets

ASPIRIN REGULAR STRENGTH

aspirin tablet, coated

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:41520-370

Route of Administration	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			
STARCH, CORN (UNII: O8232NY3SJ)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
MINERAL OIL (UNII: T5L8T28FGP)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)				
ALUMINUM OXIDE (UNII: LM26O6933)				
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)

