

CAREONE ASPIRIN- aspirin tablet, film coated
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.

American Sales Company Aspirin Drug Facts

Active ingredient (in each tablet)

Aspirin 325 mg (NSAID*)

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
- colds
- minor pain of arthritis
- headache
- toothache
- muscle pain
- menstrual pain
- temporarily reduces fever

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 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 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

- an 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
 - fever gets worse or lasts more than 3 days
 - redness or swelling is present
 - fever gets worse or lasts more than 3 days
 - new symptoms occur
 - 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 (1-800-222-1222).

Directions

- drink a full glass of water with each dose
- adults and children 12 years and over: take 1 or 2 tablets every 4 hours or 3 tablets every 6 hours, not to exceed 12 tablets in 24 hours
- children under 12 years: consult a doctor

Other information

- store at 20°-25°C (68°-77°F)

Inactive ingredients

corn starch, dibasic calcium phosphate dihydrate, hypromellose, talc, triacetin

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to the active ingredient in Bayer® Aspirin

ASPIRIN

325mg

Pain Reliever/Fever Reducer (NSAID)

For Adults

Safe Pain Relief Plus Lifesaving Benefits

Talk to your doctor or other healthcare provider before using this product for your heart.

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

300 COATED TABLETS

Drug Facts (continued)

Allergy alert: Aspirin may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ 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 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

DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

PEEL BACK HERE

CAREone®

NDC 41520-651-87

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ASPIRIN

325mg

Pain Reliever/Fever Reducer (NSAID)

For Adults

Safe Pain Relief Plus Lifesaving Benefits

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Drug Facts (continued)

■ you have high blood pressure, heart disease, liver cirrhosis, or kidney disease ■ you are taking a diuretic ■ you have asthma

As a doctor or pharmacist before use if you are taking a prescription drug for ■ gout ■ diabetes ■ arthritis

Stop use and ask a doctor if

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Inactive ingredients corn starch, dibasic calcium phosphate dihydrate, hypromellose, talc, triacetin

Questions or comments? 1-800-719-9260

**This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Bayer® Aspirin.

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Quality guaranteed or your money back.



CAREONE ASPIRIN

aspirin tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-651
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)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TALC (UNII: 7SEV7J4R1U)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	14mm
Flavor		Imprint Code	Aspirin;L
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-651-87	300 in 1 BOTTLE; Type 0: Not a Combination Product	07/25/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/25/2019	

Labeler - American Sales Company (809183973)