

**CARE ONE ASPIRIN- aspirin tablet, chewable**  
**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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**American Sales Company Aspirin 81 mg 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

**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 pain reliever/fever reducer
- for at least 7 days after tonsillectomy or oral surgery unless directed by a doctor

**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 have asthma
- you are taking a diuretic

**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
  - 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
  - new symptoms occur
  - 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. (1-800-222-1222)

**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 while symptoms persist.

Do not exceed 48 tablets in 24 hours or as directed by a doctor.

- children under 12 do not use unless directed by a doctor

**Other information**

- store at 20°-25°C (68°-77°F)

**Inactive ingredients**

corn starch, dextrose excipient, FD&C yellow #6 aluminum lake, flavors, saccharin sodium

**Questions or comments?**

1-800-719-9260

**Principal Display Panel**

Compare to Active Ingredient in St. Joseph® Chewable Aspirin

Adult Low Strength

ASPIRIN

81 mg

Pain Reliever (NSAID)

Actual Size

Chewable Orange Flavor

Aspirin Regimen

Gluten Free

36 TABLETS



## CARE ONE ASPIRIN

aspirin tablet, chewable

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-259
Route of Administration	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
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

**Product Characteristics**

Color	ORANGE (Light Orange)	Score	no score
Shape	ROUND	Size	8mm
Flavor	ORANGE	Imprint Code	L467
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-259-68	1 in 1 CARTON	11/22/2005	
1		36 in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	11/22/2005	

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

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American Sales Company