

**CAREALL ASPIRIN- aspirin tablet, chewable**  
**New World Imports, Inc**

*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**

Aspirin 81 mg (NSAID\*)

\*nonsteroidal anti-inflammatory drug

**Purpose**

Pain reliever / fever reducer

**Keep out of reach of children.**

In case of accidental overdose, contact a doctor or Poison Control Center immediately.

**Uses**

Temporary relief of minor aches and pains or as recommended by your doctor. To reduce 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 NSAID, which may cause severe stomach bleeding. The chance is higher if the user:

- Has had stomach ulcers or bleeding problems
- Takes a blood thinning (anticoagulant) or steroid drug
- Takes other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- Takes more or for a longer time than directed
- Is age 60 or older
- Has 3 or more alcoholic drinks every day while using this product

**Do not use:** if you are allergic to aspirin or other pain relievers / fever reducers. 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 user

- user has history of stomach problems, such as heartburn
- User has high blood pressure, heart disease, liver cirrhosis, or kidney disease
- User is 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:**

- User experiences any of the following signs of stomach bleeding: feels faint, vomits blood, has bloody or black stools, has stomach pain that does not get better
- An allergic reaction occurs. Seek medical help help right away
- New symptoms occur
- Redness or swelling is present
- Pain gets worse or lasts for more than 10 days
- Ringing in the ears or loss of hearing occurs
- You may report side effects to 1-888-952-0050**

**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 unborn child or complications during delivery.

**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: consult a doctor

**Inactive Ingredients**

corn starch, dextrates, FD C yellow 6, flavor, saccharin sodium

NDC 51824-057-36

CAREALL

Compare to active ingredient of St. Joseph Aspirin\*\*

Chewable

# Aspirin

Orange Flavor

- ▶ Pain Reliever
- ▶ Fever Reducer

SEE NEW WARNINGS INFORMATION



36

Low Dose Aspirin Tablets (NSAID), 81 mg each

## Drug Facts

**Active ingredient (in each tablet)** Aspirin 81 mg (NSAID)\*  
**Purposes** Pain reliever/fever reducer  
 \*nonsteroidal anti-inflammatory drug

**Uses** ■ temporary relief of minor aches and pains or as recommended by your doctor  
 ■ to reduce 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

Drug facts continued on inside panel

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IMPRINT AREA

### Drug Facts (continued)

■ are age 60 or older ■ have had stomach ulcers or bleeding problems ■ take a blood thinner (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 ■ this product 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 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 ■ redness or swelling is present ■ new symptoms occur ■ ringing in the ears or loss of hearing occurs  
 ■ You may report side effects to 1-888-952-0050

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

### Drug Facts (continued)

unborn child or complications during delivery. Keep out of reach of children. In case of accidental 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: consult a doctor.

#### Other information

■ store at room temperature  
 ■ do not use if imprinted safety seal under cap is broken or missing

#### Inactive ingredients

corn starch, dextrates, FD&C yellow #6, flavor, saccharin sodium

#### Questions or comments?

call 1-888-952-0050 (Mon-Fri 9AM-5PM EST)

\*\*This product is not manufactured or distributed by Foundation Consumer Healthcare, owner of the registered trademark St. Joseph's® Aspirin.

## CAREALL ASPIRIN

aspirin tablet, chewable

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:51824-057

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
Dextrates (UNII: G263MI44RU)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Starch, Corn (UNII: O8232NY3SJ)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

**Product Characteristics**

Color	orange (Pale Orange)	Score	no score
Shape	ROUND (Round)	Size	8mm
Flavor		Imprint Code	AZ;013
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51824-057-36	36 in 1 BOTTLE; Type 0: Not a Combination Product	03/29/2016	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	03/29/2016	

**Labeler** - New World Imports, Inc (075372276)

Revised: 10/2019

New World Imports, Inc