

ASPIRIN- aspirin tablet, chewable
Cardinal Health

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

Major Pharmaceuticals Aspirin 81 mg Drug Facts

Active ingredient (in each tablet)

Aspirin 81 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Chewable

Low Dose

Orange Flavor

Aspirin Regimen**

Gluten Free

Purpose

Pain reliever

Uses

for the temporary relief of 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

**Aspirin is not appropriate for everyone, so be sure to talk to your doctor before you begin an aspirin regimen.

Do not use

- •if you have ever had an allergic reaction to any other 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

- •you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- •stomach bleeding warning applies to you
- •you have a history of stomach problems, such as heartburn
- •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

- •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 for more than 10 days
 - •fever gets worse or lasts for more than 3 days
 - •redness or swelling is present
 - •new symptoms occur
 - •ringing in the ears or 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.

Warning: 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 not to exceed 48 tablets in

24 hours unless directed by a doctor

- •children under 12 years: consult a doctor

Other information

- •store at 20-25°C (68-77°F)

COMPARE TO the active ingredient of BAYER® CHEWABLE ASPIRIN ***

***Major® Aspirin 81 mg is not manufactured or distributed by Bayer HealthCare LLC, distributor of Bayer Chewable A

Gluten Free

Bulk Manufacturer NDC 0904-4040-73

Inactive ingredients

corn starch, dextrose excipient, FD&C yellow no. 6 aluminum lake, flavors, saccharin sodium

Questions or comments?

1-800-616-2471

Distributed by

MAJOR PHARMACEUTICALS

31778 Enterprise Drive

Livonia, MI 48150 USA

Rev. 11/11

Repackaged by Cardinal Health

Zanesville, OH 43701

IE70130713

Principal Display Panel

Aspirin

Pain Reliever (NSAID) tablets

81 mg

Contains Approximately 2052 Tablets



Contains Approximately
2052 Tablets

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81 mg

Chewable Orange Flavor
Low Dose Aspirin Regimen**
Gluten Free

Active ingredient (in each tablet) Purpose
Aspirin 81 mg (NSAID)* Pain reliever
*nonsteroidal anti-inflammatory drug

WARNING: Keep out of reach of children.



CUSTOMER ID

See product insert for directions, precautions and warnings.

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Bulk Manufacturer NDC
0904-4040-73

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Distributed by: MAJOR PHARMACEUTICALS
31778 Enterprise Drive
Livonia, MI 48150 USA

Questions or comments? 1-800-616-2471

Repackaged by Cardinal Health
Zanesville, OH 43701

L70130913

Lot No.:

Exp. Date:

ASPIRIN

aspirin tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55154-0748(NDC:0904-4040)
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
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SACCHARIN (UNII: FST467XS7D)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	ORANGE	Score	no score
Shape	ROUND	Size	8 mm
Flavor	ORANGE	Imprint Code	L467
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55154-0748-8	2052 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/23/2011	07/31/2018

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		05/23/2011	07/31/2018

Labeler - Cardinal Health (188557102)

Establishment			
Name	Address	ID/FEI	Business Operations
Cardinal Health		188557102	REPACK(55154-0748)