

ASPIRIN CHEWABLE- aspirin 81 mg tablet
Safecor Health, LLC

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.

Active Ingredient (in each tablet)

Aspirin 81 mg (NSAID*)

*nonsteroidal anti-inflammatory drug

Purpose

Pain Reliever

Uses

for the temporary relief of minor aches and pains or as recommended by your 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
- 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 three (3) or more alcoholic drinks every day while using this
- 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

- if you have ever had an allergic reaction to this product or any of its ingredients.

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 stool
 - 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

If pregnant or breast-feeding,

ask a health professional before use.

It is especially important not to use aspirin during the last three (3) months of pregnancy unless specifically 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 accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 years: consult a doctor

Other information:

- Store at room temperature.

Inactive ingredients:

corn starch, dextrans, FD&C yellow #6 aluminum lake, orange flavor, saccharin sodium.

Principal Display Panel

Aspirin

81 mg

Chewable Tablet

Mfg: Allegiant Health

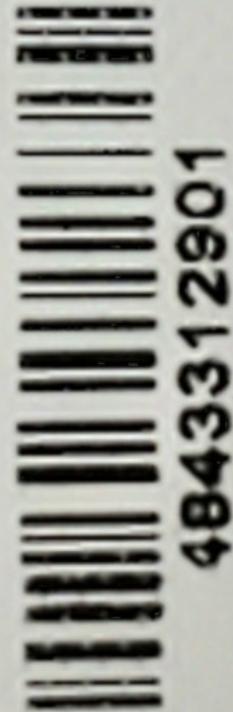
Lot:22A0131 Exp:09/06/24

PKG BY: Safecor Health

Woburn, MA

Aspirin
81 mg
Chewable Tablet

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ASPIRIN CHEWABLE

aspirin 81 mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:48433-129(NDC:69168-288)
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)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	7mm
Flavor	ORANGE	Imprint Code	AZ013
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48433-129-01	100 in 1 BOX	11/01/2022	
1		1 in 1 BLISTER PACK; 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	11/01/2022	

Labeler - Safecor Health, LLC (828269675)

Establishment

Name	Address	ID/FEI	Business Operations
Safecor Health, LLC		078805287	repack(48433-129) , relabel(48433-129)

Revised: 12/2022

Safecor Health, LLC