

ASPIRIN LOW DOSE CHEWABLE- aspirin tablet, chewable
SPIRIT PHARMACEUTICALS 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.

VALUMEDS ASPIRIN CHEWABLE

Drug Facts

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. **Because of its delayed action, this product will not provide fast relief of headaches, fever or other symptoms needing immediate relief.**
- ask your doctor about other uses for Aspirin 81 mg

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 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 other)
- 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

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 a 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 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.

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

- **each tablet contains:** sodium 0.22 mg
- save carton for full directions and warnings
- store at room temperature

Inactive ingredients

BHT (Butylated Hydroxytoluene), dextrates, FD&C Yellow#6 Aluminum Lake, microcrystalline cellulose, modified corn starch, orange flavor, pregelatinized starch, sucralose, stearic acid

Questions or comments?

1-888-333-9792

DISTRIBUTED BY

SPIRIT PHARMACEUTICALS, LLC.

RONKONKOMA, NY 11779

PRINCIPAL DISPLAY PANEL - 36 COUNT BOTTLE CARTON

VALUMEDS™

Compare to the active ingredient in

Bayer® Chewable Low Dose

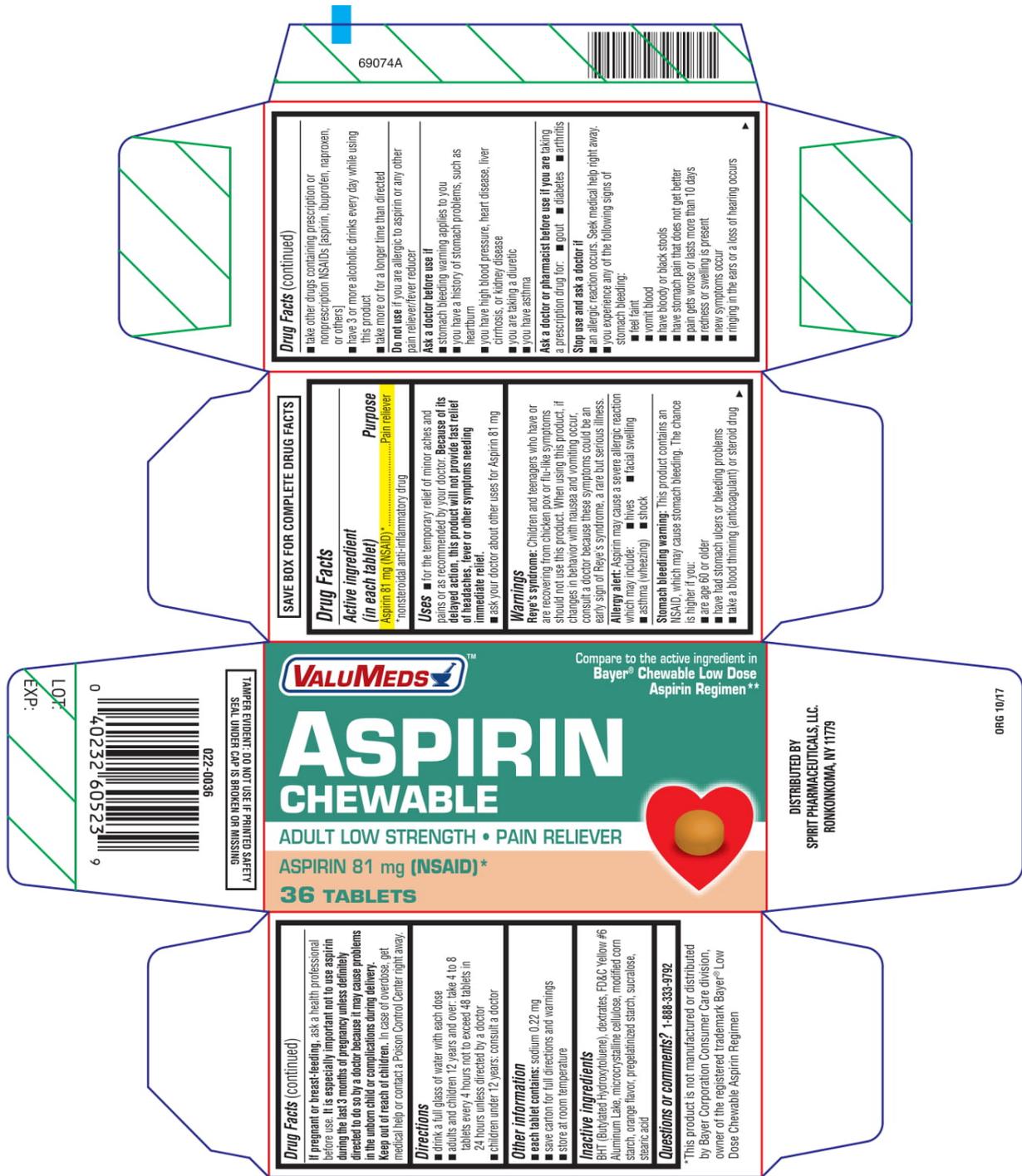
Aspirin Regimen**

ASPIRIN CHEWABLE

ADULT LOW STRENGTH PAIN RELIEVER

ASPIRIN 81 mg (NSAID)*

36 TABLETS



ASPIRIN LOW DOSE CHEWABLE

aspirin tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0220
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
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
DEXTRATES (UNII: G263MI44RU)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	
ORANGE (UNII: 5EVU04N5QU)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	UPPER;tc1334;LOWER;PLAIN
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0220-3	1 in 1 CARTON	04/11/2018	
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	04/11/2018	

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)**Establishment**

Name	Address	ID/FEI	Business Operations
Time Cap Laboratories, Inc.		037052099	manufacture(68210-0220)