# CHEWABLE ASPIRIN ADULT LOW DOSE- as pirin tablet, chewable Medline Industries

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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## Aspirin 81 mg chewable orange 36/BT

### 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 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
- 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 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
- do not use if imprinted safety seal under cap is broken or missing

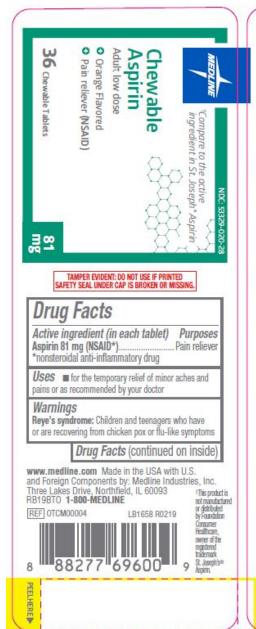
#### **Inactive ingredients**

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

#### **Questions or comments?**

### 1-888-952-0050

(Monday-Friday 9AM-5PM EST)



#### Drug Facts (continued)

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

#### CHEWABLE ASPIRIN ADULT LOW DOSE

aspirin tablet, chewable

#### **Product Information** NDC:53329-020 HUMAN OTC DRUG Product Type Item Code (Source) 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
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ORANGE PEEL (UNII: TI9T76XD44)	
STARCH, CORN (UNII: O8232NY3SJ)	
DEXTRATES (UNII: G263MI44RU)	
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)	

Product Characteristics					
Color	orange	Score	score with uneven pieces		
Shape	ROUND	Size	7mm		
Flavor	ORANGE	Imprint Code	AZ;013		
Contains					

Packaging					
# Item Co	de Package D	escription	Marketing Start Date	Marketing End Date	
1 NDC:53329-0	20- 36 in 1 BOTTLE, PLASTIC; Typ Product	pe 0: Not a Combination	0 4/17/20 18		



Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part343	04/17/2018				

## Labeler - Medline Industries (025460908)

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