

**CHEWABLE ASPIRIN ADULT LOW DOSE- aspirin 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)



TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

### Drug Facts

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

**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

Drug Facts (continued on inside)

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[REF] OTCM00004 LB1658 R0219



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

### Drug Facts (continued)

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- 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
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**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

### Drug Facts (continued)

- redness or swelling is present ■ new symptoms occur
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#### Questions or comments?

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## CHEWABLE ASPIRIN ADULT LOW DOSE

aspirin tablet, chewable

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53329-020
<b>Route of Administration</b>	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: T19T76XD44)	
STARCH, CORN (UNII: O8232NY3SJ)	
DEXTRATES (UNII: G263MI44RU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-020-28	36 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/17/2018	



### 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)

Revised: 12/2019

Medline Industries