

**CHEWABLE ASPIRIN ADULT LOW DOSE- aspirin tablet, chewable**  
**Medline Industries, LP**

*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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**020 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, dextrans, FD&C yellow #6 aluminum lake, orange flavor, saccharin sodium

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

Call toll free **1-800-MEDLINE (633-5463)**

Monday-Friday (9AM-5PM CST)

### **Manufacturing information**

Manufactured by:

Medline Industries, LP

Three Lakes Drive, Northfield, IL 60093 USA

Made in the USA with U.S. and Foreign Components

[www.medline.com](http://www.medline.com)

1-800-MEDLINE (633-5463)

REF: OTCM00004

V1 RH22HND

### **Package Label**



NDC: 53329-020-28



# Adult Low Dose Chewable Aspirin

Pain Reliever (NSAID)\*  
■ Orange Flavored

\*Compare to the active ingredient in Bayer® Low Dose

**36** CHEWABLE TABLETS**81 mg****TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.**

## Drug Facts

**Active ingredient (in each tablet)**  
Aspirin 81 mg (NSAID)\*  
\*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 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 ■ shock ■ asthma (wheezing)**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, ▶**[REF] OTCM00004 (CONTINUED ON BACK OF LABEL)**This product is not manufactured or distributed by Bayer Healthcare LLC, owner of the registered trademark Bayer® Chewable Aspirin. [www.medline.com](http://www.medline.com) Made in the USA with U.S. and Foreign Components. Manufactured for Medline Industries, LP, Three Lakes Drive, Northfield, IL 60093 USA 1-800-MEDLINE V1 R422-HND**8 88277 69600 9**LOT  
EXP**PEEL HERE**

## Drug Facts (continued)

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 stools ■ have stomach pain that does not get better ■ pain gets worse or lasts for 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 right away.****Directions** ■ drink a full glass of water with each dose ■ adults and children 12 years and older: 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, dextrates, FD&C yellow #6 aluminum lake, orange flavor, saccharin sodium

## Questions or comments?

Call toll free 1-800-MEDLINE (633-5463)  
Monday - Friday 9AM - 5PM CST

# 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
<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>ORANGE PEEL</b> (UNII: T19T76XD44)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>DEXTRATES</b> (UNII: G263MI44RU)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	

## Product Characteristics

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

## 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

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

**Labeler** - Medline Industries, LP (025460908)

Revised: 9/2022

Medline Industries, LP