

## **ASPIRIN- aspirin tablet, chewable**

### **Major Pharmaceuticals**

*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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### **Major Pharmaceuticals Aspirin 81 mg Drug Facts**

#### **Active ingredient (in each chewable tablet)**

Aspirin 81 mg (NSAID\*)

\*nonsteroidal anti-inflammatory drug

#### **Purpose**

Pain reliever

#### **Uses**

for the temporary relief of minor aches and pains

#### **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 have ever had an allergic reaction to any other pain reliever/fever reducer
- for at least 7 days after tonsillectomy or oral surgery unless directed by a doctor

### **Ask a doctor before use if**

- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- 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
  - fever gets worse or lasts for more than 3 days
  - redness or swelling is present
  - new symptoms occur
  - ringing in the ears or loss of hearing occurs

These could be signs of a serious condition

### **If pregnant or breast-feeding,**

ask a health professional before use. It is especially important not to use aspirin at 20 weeks or later in 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 (1-800-222-1222).

### **Directions**

- drink a full glass of water with each dose
- adults and children 12 years and over: take 4 to 8 chewable 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 20-25°C (68-77°F)

### **Inactive ingredients**

corn starch, dextrose excipient, FD&C yellow no. 6 aluminum lake, flavors, saccharin sodium

### **Questions or comments?**

**1-800-616-2471**

### **Principal Display Panel**

MAJOR<sup>®</sup>

COMPARE TO the active ingredient of BAYER<sup>®</sup> CHEWABLE ASPIRIN

Aspirin 81 mg

Pain Reliever (NSAID)

Chewable

Orange Flavor

Aspirin Regimen

Low Dose

Actual Size

36 Tablets

Talk to your doctor or other healthcare provider before using this product for your heart.

See New Warning



**ASPIRIN**  
aspirin tablet, chewable

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:0904-4040

NDC 0904-4040-73

COMPARE TO the active ingredient of  
BAYER® CHEWABLE ASPIRIN\*\*

**MAJOR®**

**Aspirin 81mg**  
Pain Reliever (NSAID)

**Chewable** Orange Flavor

**Low Dose** Actual Size  
See New Warning

**36 Tablets**

Aspirin Regimen  
Talk to your doctor or other healthcare provider  
before using this product for your heart.

46768 5C C6

DO NOT USE IF PRINTED SEAL UNDER  
CAP IS BROKEN OR MISSING

3 09044 04073 8

**Drug Facts (continued)**

- pain gets worse or lasts more than 10 days
  - fever gets worse or lasts more than 3 days
  - redness or swelling is present
  - new symptoms occur
  - ringing in the ears or a loss of hearing occurs
  - These could be signs of a serious condition
  - If pregnant or breast-feeding,** ask a health professional before use. It is especially important not to use aspirin at 20 weeks or later in pregnancy, unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.
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- Directions**
- drink a full glass of water with each dose
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  - children under 12 years: consult a doctor
- Other information**
- store at 20°-25°C (68°-77°F)

**Drug Facts (continued)**

- 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 have ever had an allergic reaction to any other pain reliever/fever reducer
- for at least 7 days after tonsilectomy or oral surgery unless directed by a doctor
- 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

**Drug Facts**

- Active ingredient (in each chewable tablet)** Pain reliever Aspirin 81 mg (NSAID)\*.....
- Purpose** Nonsteroidal anti-inflammatory drug
- Uses** for the temporary relief of minor aches and pains
- 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
  - asthma (wheezing)
  - facial swelling
  - shock
  - anaphylaxis
- 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
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**Drug Facts (continued)**

**Questions or comments?**  
1-800-616-2471

**Inactive ingredients** corn starch, dextrose expellent, FD&C yellow no. 6 aluminum lake, flavors, saccharin sodium

**MAJOR® PHARMA CEUTICALS**  
LIVONIA, MI 48152  
M-05 REV. 02/22  
Re-Order No. 700317

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<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>	<b>Strength</b>		
	FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
	SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
	STARCH, CORN (UNII: O8232NY3SJ)			
<b>Product Characteristics</b>				
<b>Color</b>	ORANGE	<b>Score</b>	no score	
<b>Shape</b>	ROUND	<b>Size</b>	8mm	
<b>Flavor</b>	ORANGE	<b>Imprint Code</b>	L467	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0904-4040-73	1 in 1 CARTON	12/12/2007	
1		36 in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<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	12/12/2007		

**Labeler** - Major Pharmaceuticals (191427277)

Revised: 2/2023

Major Pharmaceuticals