

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

### **Major Pharmaceuticals**

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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**

- 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
- 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?**

**1-800-719-9260**

## **Principal Display Panel**

MAJOR<sup>®</sup>

Compare to the active ingredient in Bayer<sup>®</sup> Chewable Low Dose Aspirin

Chewable

Aspirin

81 mg

Actual Size

Pain Reliever (NSAID)

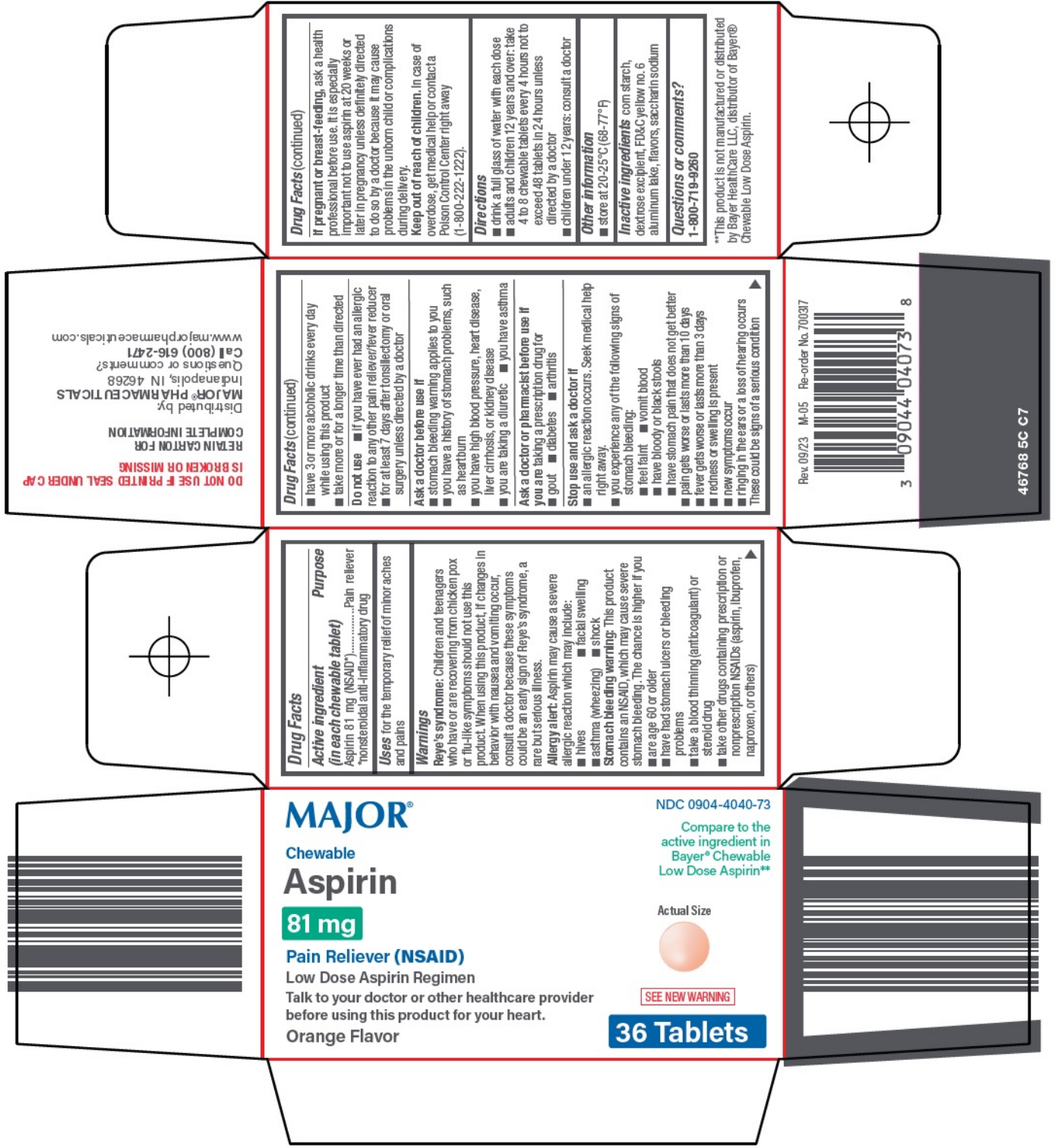
Low Dose Aspirin Regimen

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

SEE NEW WARNING INFORMATION

Orange Flavor

36 Tablets



# ASPIRIN

aspirin tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-4040
Route of Administration	ORAL		

**MAJOR**  
Chewable  
**Aspirin**

**81 mg**

**Pain Reliever (NSAID)**

Low Dose Aspirin Regimen

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

Orange Flavor

**36 Tablets**

Actual Size



SEE NEW WARNING

NDC 0904-4040-73

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

**Drug Facts**  
**Active ingredient (in each chewable tablet)** Purpose  
Aspirin 81 mg (NSAID).....Pain reliever  
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 ■ 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)

**Drug Facts (continued)**  
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 Poison Control Center right away (1-800-222-1222).

**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)

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

**Questions or comments?**  
1-800-719-9260

Rev. 09/23 M-05 Re-order No. 700317  
3 09044 404073 8  
46768 5C C7

DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING  
RETAIN CARTON FOR COMPLETE INFORMATION  
Distributed by  
MAJOR® PHARMACEUTICALS  
Indianapolis, IN 46268  
Call (800) 616-2471  
www.majorpharmaceuticals.com

**Drug Facts (continued)**  
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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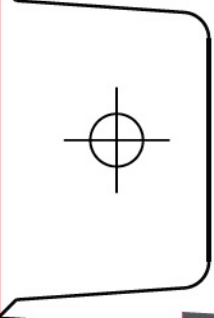
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**Inactive ingredients** corn starch, dextrose excipient, FD&C yellow no. 6 aluminum lake, flavors, saccharin sodium

**Questions or comments?**  
1-800-719-9260

\*\*This product is not manufactured or distributed by Bayer Healthcare LLC, distributor of Bayer® Chewable Low Dose Aspirin.



**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

**Inactive Ingredients**

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

**Product Characteristics**

Color	ORANGE	Score	no score
Shape	ROUND	Size	8mm
Flavor	ORANGE	Imprint Code	L467
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-4040-73	1 in 1 CARTON	12/12/2007	
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 Drug	M013	12/12/2007	

**Labeler** - Major Pharmaceuticals (191427277)

Revised: 8/2024

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