

**ASPIRIN LOW DOSE CHEWABLE ORANGE- aspirin tablet, chewable**  
**Cardinal Health 107, LLC**

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**Drug Facts**

**Active ingredient (in each tablet)**

Aspirin 81mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

**Purpose**

Pain reliever

**Uses**

- for the temporary relief of minor aches and pains or as recommended by your doctor
- ask your doctor about other uses for Chewable Aspirin 81 mg

**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
- 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 have asthma
- you are taking a diuretic

### **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 more than 10 days
  - fever get worse or lasts more than 3 days
  - redness or swelling is present
  - ringing in the ears or loss of hearing occurs
  - any new symptoms occur

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 during the last 3 months of 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 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 over

take 4 to 8 tablets every 4 hours not  
exceed 48 tablets in 24 hours unless  
directed by a doctor

children under 12 years

consult a doctor

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### **Other information**

- store at room temperature (15<sup>0</sup>-30<sup>0</sup>C)
- **Tamper Evident:** do not use if sealed blister units are broken or damaged

Distributed By:

Cardinal Health

Dublin, OH 43017

L5920616-10624

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### **Inactive ingredients**

corn starch, dextrose monohydrate, FD&C yellow #6, orange flavor, silicon dioxide, sodium saccharine, stearic acid

### **Questions or comments?**

**1-800-616-2471**

### **Principal Display Panel**

ASPIRIN LOW DOSE CHEWABLE

ORANGE PAIN RELIEVER (NSAID) TABLETS

81 mg

10 CHEWABLE TABLETS



L121

NDC 55154-2635-0

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ORANGE PAIN RELIEVER (NSAID) TABLETS  
81 mg**

**10 CHEWABLE TABLETS**

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Uses ■ for the temporary relief of minor aches and pains or as recommended by your doctor ■ ask your doctor about other uses for Chewable Aspirin 81 mg

**Directions**

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children under 12 years consult a doctor

STORAGE: Store at room temperature (15° - 30°C)

**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.

**Warning:** This Unit Dose package is not child resistant and is Intended for Institutional Use Only. Keep this and all drugs out of the reach of children. 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 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.

**Tamper Evident:** do not use if sealed blister units are broken or damaged

Questions or comments? 1-800-616-2471

Packaged and Distributed by:

MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268 USA

Distributed by Cardinal Health

Dublin, OH 43017

L5920616-10624

Lot: Exp:

Distributed by Cardinal Health

Dublin, OH 43017

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**Warnings Cont.**

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Do not use ■ if you are allergic to aspirin or 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 have asthma ■ you are taking a diuretic

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 more than 10 days ■ fever get worse or lasts more than 3 days ■ redness or swelling is present ■ ringing in the ears or loss of hearing occurs ■ any new symptoms occur. These could be signs of a serious condition

## ASPIRIN LOW DOSE CHEWABLE ORANGE

aspirin tablet, chewable

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55154-2635(NDC:0904-6794)
<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
STARCH, CORN (UNII: O8232NY3SJ)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	PH034
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55154-2635-0	10 in 1 BAG	06/25/2024	
1		1 in 1 BLISTER PACK; 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	06/25/2024	

**Labeler** - Cardinal Health 107, LLC (118546603)

### Establishment

Name	Address	ID/FEI	Business Operations
Safecor Health, LLC		828269675	REPACK(55154-2635)

Revised: 6/2024

Cardinal Health 107, LLC