

**ASPIRIN- aspirin tablet, chewable**  
**Publix Super Markets Inc**

*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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**Publix Super Markets, Inc. Chewable Aspirin 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 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.

### **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 68-77°F (20-25°C)

### **Inactive ingredients**

corn starch, D&C red #27 aluminum lake, dextrose excipient, FD&C red #40 aluminum lake, flavors, saccharin sodium

### **Principal Display Panel**

p

LOW DOSE

chewable aspirin

81 mg

PAIN RELIEVER (NSAID)

- Cherry flavor

ASPIRIN REGIMEN

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

ACTUAL SIZE

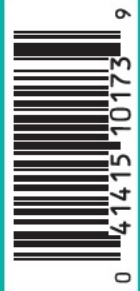
SEE NEW WARNING

36 TABLETS

Compare to Bayer® Chewable Low Dose Aspirin active ingredient

27468 63 C9

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



**Drug Facts**

**Active ingredient (in each chewable tablet)**  
Aspirin 81 mg (NSAID)<sup>1</sup>.....Pain reliever  
<sup>1</sup>nonsteroidal anti-inflammatory drug

**Purpose**  
Uses for the temporary relief of minor aches and pains

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- hives
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- 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

**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 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
  - 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 (continued)**

■ pain gets worse or lasts more than 10 days

■ fever gets worse or lasts more than 3 days

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**Other information**

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NDC 56062-274-68

LOW DOSE **chewable aspirin**

81 mg PAIN RELIEVER (NSAID)  
• Cherry flavor

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

**36 TABLETS**



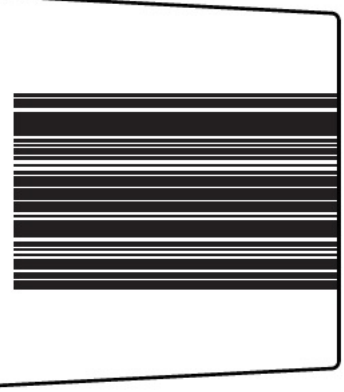
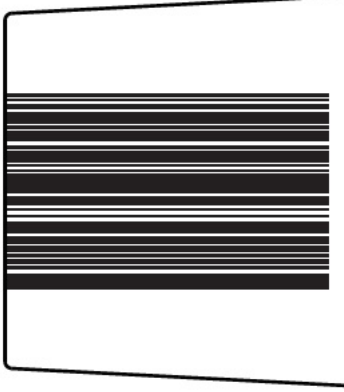
ACTUAL SIZE  
**SEE NEW WARNING**

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

**Publix**

**Drug Facts (continued)**  
**Inactive ingredients:** corn starch, D&C red #27 aluminum lake, dextrose excipient, FD&C red #40 aluminum lake, Flavors, saccharin sodium

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The owner of the registered trademark Bayer®.



**ASPIRIN**  
aspirin tablet, chewable

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:56062-274
<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>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	

### Product Characteristics

<b>Color</b>	PINK	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	8mm
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	L274
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-274-68	1 in 1 CARTON	08/24/1998	
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 not final	part343	08/24/1998	

**Labeler** - Publix Super Markets Inc (006922009)