

**PUBLIX SUPER MARKETS INC- acetaminophen, aspirin and caffeine tablet**  
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**1205-PBX-2024-0614**

***Drug Facts***

**Active ingredient(s)**

Acetaminophen 250 mg

Aspirin 250 mg (NSAID\*)

Caffeine 65 mg

\*nonsteroidal anti-inflammatory drug

**Purpose**

Pain reliever

Pain reliever

Pain reliver aid

**Use**

■ treats migraine

**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**

Acetaminophen may cause severe skin reactions. Symptoms may include:

■ skin reddening

■ blisters

■ rash

If a skin reaction occurs, stop use and seek medical help right away.

**Allergy alert**

Aspirin may cause a severe allergic reaction which may include:

■ hives

■ facial swelling

■ asthma (wheezing)

- shock

### **Liver warning**

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 2 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

### **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

### **Medication overuse headache warning**

Headaches may worsen if this product is used for 10 or more days per month.

### **Caffeine warning**

The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat.

### **Do not use**

- if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist

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

- you have never had migraines diagnosed by a health professional
- you have a headache that is different from your usual migraines
- you have the worst headache of your life
- you have fever and stiff neck
- you have headaches beginning after or caused by head injury, exertion, coughing or bending
- you experienced your first headache after the age of 50
- you have daily headaches

- you have a migraine so severe as to require bed rest
- you have liver disease
- 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 have problems or serious side effects from taking pain relievers or fever reducers
- you have vomiting with your migraine headache

**Ask a doctor or pharmacist before use if you are**

- taking a prescription drug for:
  - diabetes
  - gout
  - arthritis
- under a doctor's care for any serious condition
- taking any other drug
- taking any other product that contains aspirin, acetaminophen, or any other pain reliever/fever reducer

**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
- your migraine is not relieved or worsens after first dose
- new or unexpected 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 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). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

■ **do not use more than directed**

- adults: take 2 caplets with a glass of water
- if symptoms persist or worsen, ask your doctor
- do not take more than 2 caplets in 24 hours, unless directed by a doctor
- under 18 years of age: ask a doctor

**Other information**

- store at controlled room temperature 20° to 25°C (68° to 77°F)
- close cap tightly after use
- read all product information before using.
- keep this box for important information

**Inactive ingredients**

carnauba wax, hydroxypropyl cellulose, hypromellose, microcrystalline cellulose, polyethylene glycol, sodium stearyl fumarate, titanium dioxide

**PRINCIPAL DISPLAY PANEL**

migrainerelief

NDC 56062-305-02

ACETAMINOPHEN, ASPIRIN (NSAID) & CAFEINE TABLETS

PAIN RELIEVER / PAIN RELIEVER AID

Actual Size

50 COATED CAPLETS\*\*

\*\*CAPSULE-SHAPED TABLETS

†Compare to the active ingredients in Excedrin® Migraine



## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
<b>CAFFEINE</b> (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>SODIUM STEARYL FUMARATE</b> (UNII: 7CV7WJK4UI)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>HYDROXYPROPYL CELLULOSE (110000 WAMW)</b> (UNII: 5Y0974F5PW)	
<b>HYPROMELLOSE 2910 (6 MPA.S)</b> (UNII: 0WZ8WG20P6)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (Capsule Shaped Tablet)	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	I1
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-305-02	1 in 1 CARTON	02/23/2024	
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214039	02/23/2024	

**Labeler** - PUBLIX SUPER MARKETS INC (006922009)