

**HEADACHE RELIEF- acetaminophen, aspirin, caffeine tablet, film coated**  
**Publix Super Markets Inc**

-----  
**Publix 44-334B**

***Active ingredients (in each caplet)***

Acetaminophen 250 mg

Aspirin 250 mg (NSAID)\*

Caffeine 65 mg

\*nonsteroidal anti-inflammatory drug

***Purpose***

Pain reliever

Pain reliever

Pain reliever aid

***Uses***

- temporarily relieves minor aches and pains due to:
  - headache
  - arthritis
  - a cold
  - muscular aches
  - toothache
  - premenstrual and menstrual cramps

***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:

- shock
- facial swelling
- hives
- asthma (wheezing)

**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.

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- 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
- 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
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take more or for a longer time than directed

**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 heart beat.

#### **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.
- if you have ever had an allergic reaction to this product or any of its ingredients

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

- 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 have asthma
- you are taking a diuretic

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

- taking a prescription drug for diabetes, gout, or arthritis
- taking any other drug or are under a doctor's care for any serious condition

#### **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
- ringing in the ears or a loss of hearing occurs
- redness or swelling is present
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- 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 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 accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

### **Directions**

- **do not take more than directed**
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 caplets every 6 hours. Do not take more than 8 caplets in 24 hours.
- children under 12 years: ask a doctor

### **Other information**

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

### **Inactive ingredients**

corn starch, crospovidone, hypromellose, microcrystalline cellulose, povidone, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide

### **Principal display panel**

NDC 56062-934-12

EXTRA STRENGTH

**headache**relief

**ACETAMINOPHEN**

**ASPIRIN (NSAID), CAFFEINE**

**PAIN RELIEVER/PAIN RELIEVER AID**

ACTUAL SIZE

**100 CAPLETS**

†Compare to the active ingredients  
in Excedrin® Extra Strength Caplets

†This product is not manufactured or distributed by GSK Consumer  
Healthcare SARL, owner of the registered trademark Excedrin® Extra  
Strength Caplets. 50844 REV1121B33412

DISTRIBUTED BY PUBLIX SUPER MARKETS, INC.,  
3300 PUBLIX CORPORATE PARKWAY  
LAKELAND, FL 33811  
1-888-267-3037 **publix.com**

**PUBLIX GUARANTEE:** COMPLETE SATISFACTION  
OR YOUR MONEY BACK

**PUBLIX®**

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS  
BROKEN OR MISSING**

Lot no. & Exp. Date



TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING



EXTRA STRENGTH headach relief ACETAMINOPHEN ASPIRIN (NSAID), CAFFEINE PAIN RELIEVER/PAIN RELIEVER AID

NDC 56062-934-12



100 CAPLETS

Compare to the active ingredients in Excedrin Extra Strength Caplets



NDC 56062-934-12

EXTRA STRENGTH headach relief ACETAMINOPHEN ASPIRIN (NSAID), CAFFEINE PAIN RELIEVER/PAIN RELIEVER AID

100 CAPLETS

Compare to the active ingredients in Excedrin Extra Strength Caplets

B-1518-334B-12 REV1121833412

Drug Facts (continued)

- never take more than 3 days... If pregnant or breast-feeding... Directions: do not take more than directed... Other information: store at 25°C (77°F)...

Inactive ingredients

hydroxypropyl methylcellulose, polyethylene glycol, sodium lauryl sulfate...

This product is not manufactured or distributed by GSK Consumer Healthcare SARL...



publix 3300 PUBLIX CORPORATE PARKWAY LAKE LAND, FL 33811

PUBLIC GUARANTEE: COMPLETE SATISFACTION OR YOUR MONEY BACK

Drug Facts (continued)

- have had stomach ulcers or bleeding problems... Do not use: if you have ever had an allergic reaction... Ask a doctor before use if: you have liver disease...

Stop use and ask a doctor if

- an allergic reaction occurs... you experience any of the following signs of stomach bleeding: feel faint, vomit blood...

Publix 44-334

HEADACHE RELIEF

acetaminophen, aspirin, caffeine tablet, film coated

Product Information

Table with 4 columns: Product Type (HUMAN OTC DRUG), Route of Administration (ORAL), Item Code (Source) (NDC:56062-934)

**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>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	44;334
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-934-12	1 in 1 CARTON	09/24/2021	
1		100 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
OTC Monograph Drug	M013	09/24/2021	

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

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(56062-934)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		832867837	manufacture(56062-934)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		832867894	manufacture(56062-934)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		967626305	pack(56062-934)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		117025878	manufacture(56062-934)

Revised: 9/2023

Publix Super Markets Inc