

**LIL DRUG STORE HEADACHE RELIEF EXTRA STRENGTH- acetaminophen,  
aspirin, and caffeine tablet  
Lil' Drug Store Products, Inc.**

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**Lil' Drug Store <sup>®</sup> Headache Relief**

**Extra Strength**

***Drug Facts***

<b><i>Active ingredients (in each tablet)</i></b>	<b><i>Purpose</i></b>
Acetaminophen 250 mg	Pain reliever
Aspirin 250 mg (NSAID *)	Pain reliever
Caffeine 65 mg	Pain reliever aid

\* nonsteroidal anti-inflammatory drug

**Uses**

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

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

**Liver warning**

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

- more than 8 tablets 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

### **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.

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

- you have liver disease
- the 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**

- any other drug containing an NSAID (prescription or nonprescription)
- a blood thinning (anticoagulant) drug such as warfarin
- a steroid drug
- a prescription drug for diabetes, gout, or arthritis
- any other drug, or are under a doctor's care for any serious condition

### **When using this product**

- take with food or milk if stomach upset occurs

### **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 loss of hearing occurs
- painful area is red or swollen
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- any new symptoms appear

**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. 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**
- drink a full glass of water with each dose

<ul style="list-style-type: none"> <li>• adults and children 12 years and over</li> </ul>	<p>take 2 tablets every 6 hours; not more than 8 tablets in 24 hours.</p>
<ul style="list-style-type: none"> <li>• children under 12 years</li> </ul>	<p>ask a doctor</p>

### Other information

- **do not use if carton or pouch is open or damaged**
- store at room temperature 59-86°F (15-30°C)
- avoid excessive heat and humidity
- see bottom panel of carton or pouch for expiration date and lot number

### Inactive ingredients

hypromellose, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, starch, stearic acid, titanium dioxide

### Questions or comments?

call toll-free 1-877-507-6516 (M-F 8 AM-4:30PM CST)

### PRINCIPAL DISPLAY PANEL - 4 Tablet Pouch Carton

**Compare to the Active Ingredients in  
Excedrin <sup>®</sup>\***

**Pain Reliever/Pain Reliever Aid**

***Lil'***  
**DrugStore <sup>®</sup>**

***Headache  
Relief***

***EXTRA  
STRENGTH***

***Acetaminophen, Aspirin (NSAID) and Caffeine***

***4 TABLETS***

Compare to the Active Ingredients in  
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Pain Reliever/Pain Reliever Aid



# Headache Relief

## EXTRA STRENGTH

Acetaminophen, Aspirin (NSAID) and Caffeine

**4 TABLETS**

**4 TABLETS**

Headache Relief



**DO NOT USE IF INNER POUCH OR CARTON IS OPEN OR DAMAGED!**

### Drug Facts

#### Active ingredients (in each tablet)

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Acetaminophen 250 mg.....	Pain reliever
Aspirin 250 mg (NSAID)*.....	Pain reliever
Caffeine 65 mg.....	Pain reliever aid

\*nonsteroidal anti-inflammatory drug

**Uses** • temporarily relieves minor aches and pains due to:  
 • headache • a cold • arthritis • muscular aches  
 • sinusitis • toothache • premenstrual & 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:  
 • hives • facial swelling • asthma (wheezing) • shock

#### Liver warning:

This product contains acetaminophen. Severe liver damage may occur if you take  
 • more than 8 tablets in 24 hours, which is the maximum daily amount  
 • with other drugs containing acetaminophen  
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**LIFT PANEL FOR CONTINUED DRUG FACTS**

**4 TABLETS** Headache Relief

**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.

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#### Directions • do not use more than directed

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- children under 12 years: ask a doctor

#### Other information

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#### Questions or comments?

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Product manufactured for:  
Lil' Drug Store Products, Inc.  
1201 Continental Place NE  
Cedar Rapids, IA 52402  
www.lildrugstore.com 97382C-US-02-12

\*This product is not manufactured or distributed by Novartis Consumer Health, Inc. Lil' Drug Store Products, Inc. does not own the Excedrin® trademark.



Headache Relief  
**4 TABLETS**

### Drug Facts (continued)

**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.

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- any new symptoms appear

## LIL DRUG STORE HEADACHE RELIEF EXTRA STRENGTH

acetaminophen, aspirin, and caffeine tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66715-9738
<b>Route of Administration</b>	ORAL		

### 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>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<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>	ROUND	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	FR9
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66715-9738-2	2 in 1 CARTON	01/27/2011	07/15/2024
-		2 in 1 POUCH; Type 0: Not a Combination		

1		Product		
2	NDC:66715-9738-4	10 in 1 VIAL; Type 0: Not a Combination Product	01/27/2011	09/12/2021
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA075794		01/27/2011	07/15/2024

**Labeler** - Lil' Drug Store Products, Inc. (093103646)

Revised: 7/2021

Lil' Drug Store Products, Inc.