EXTRA STRENGTH HEADACHE, LIL DRUG STORE- extra strenght headache relief- acetaminophen, aspirin, caffeine tablet tablet Lil' Drug Store Products, Inc.

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Headache Extra Strength, 25ct Unit Dose Box, Lil' Drug Store Products, Inc.

**Drug Facts** 

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### Active ingredients

Active ingredients (in each caplet)

Acetaminophen 250 mg

Aspirin (NSAID\*) 250 mg Caffeine 65 mg

\*nonsteroidal anti-inflammatory drug

### **Purposes**

## **Purposes**

Pain reliever

Pain reliever

Pain reliever aid

#### Uses

#### Uses

temporarily relieves minor aches and pains due to:

- headache
- a cold
- arthritis
- muscular aches
- toothache
- premenstrual & menstrual cramps

## Warnings

Warnings

# Reye's syndrome

**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

**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

Allergy alert: Aspirin (NSAIDs) may cause a severe allergic reaction which may include:

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

### Liver warning

### Liver warning:

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

- more than 8 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

**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**

**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

#### 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

#### 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

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

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

### Stop use and ask a doctor if

## 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

These could be signs of a serious condition.

# If pregnant or breast-feeding

**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.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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**

#### **Directions**

- do not use more than directed
- drink a full glass of water with each dose

adults and children (12 years 2 caplets every 6 hours as needed; not more than 8

and over) caplets in 24 hours

children under 12 years ask a doctor

#### Other information

#### Other information

- store at 68°-77°F (20°-25°C); excursions permitted between 59°-86°F (15°-30°C)
- avoid excessive heat and humidity
- each caplet contains: Magnesium 0.58 mg

#### Inactive ingredients

### Inactive ingredients

colloidal silicon dioxide, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone K30, pregelatinized starch, stearic acid, talc

#### **Ouestions or comments?**

Questions or comments?

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

Extra Strength Headache Relief, 25ct, Lil' Drug Store ®

**Extra Strength** 

**Headache Relief** 

Acetaminophen 250 mg Pain Reliever Aspirin (NSAID\*) 250 mg Pain Reliever Caffeine 65 mg Pain Reliever Aid

[caplets image]

**ACTUAL SIZE** 

**50 CPLETS** 

25 POUCHES 2 CAPLETS PER POUCH

[Lil' Drug Store ® logo]



## **EXTRA STRENGTH HEADACHE, LIL DRUG STORE**

extra strenght headache relief- acetaminophen, aspirin, caffeine tablet tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-6438(NDC:68210-0107)
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	250 mg	
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg	
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg	

Inactive Ingredients			
Ingredient Name	Strength		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
TALC (UNII: 7SEV7J4R1U)			
POVIDONE K30 (UNII: U725QWY32X)			
STARCH, CORN (UNII: O8232NY3SJ)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			

Product Characteristics				
Color	white	Score	no score	
Shape	OVAL ((capsule shaped, biconvex))	Size	18mm	
Flavor		Imprint Code	S53	
Contains				

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66715- 6438-6	25 in 1 BOX, UNIT-DOSE	04/19/2022	
1		2 in 1 POUCH; 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	04/19/2022	

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

Revised: 12/2023 Lil' Drug Store Products, Inc.