

**EXTRA STRENGTH HEADACHE, CIRCLE K- acetaminophen/aspirin/caffeine tablet tablet**

**EXTRA STRENGTH HEADACHE- acetaminophen/aspirin/caffeine tablet tablet  
Lil' Drug Store Products, Inc.**

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**Extra Strength Headache (LD/CK)**

### ***Drug Facts***

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

Acetaminophen 250 mg

Aspirin 250 mg (NSAID)\*

Caffeine 65 mg

\*nonsteroidal anti-inflammatory drug

#### ***Purposes***

Pain reliever

Pain reliever

Pain reliever aid

#### ***Uses***

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

#### **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:** Aspirin may cause a severe allergic reaction, which may include:

- hives
- facial swelling
- asthma (wheezing)

- shock

## **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.

## **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**

- 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
- 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 prescription drug for diabetes, gout, or arthritis
- any other drug or are under a doctor's care for any serious condition
- a blood thinning (anticoagulant) or steroid drug

**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**, 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.**

**Overdose warning**

**Overdose warning:** 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 (see Overdose warning)
- 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 between 20°-25°C (68°-77°F)

## Inactive ingredients

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

## Questions or comments?

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

## PDP (Lil' Drug)

[caduceus]

Compare to the Active  
Ingredients in Excedrin®  
Extra Strength\*\*

## Extra Strength Headache

### Acetaminophen 250 mg

Pain Reliever

Aspirin (NSAID) 250 mg Pain Reliever

Caffeine 65 mg Pain Reliever Aid

[caplets image]

ACTUAL SIZE

**50**

## Caplets [Lil' Drug Store Logo]

<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>• 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</li> <li>• ringing in the ears or loss of hearing occurs</li> <li>• painful area is red or swollen</li> <li>• pain gets worse or lasts for more than 10 days</li> <li>• fever gets worse or lasts for more than 3 days</li> <li>• any new symptoms appear</li> </ul> <p>These could be signs of a serious condition.</p> <p><b>If pregnant or breast-feeding</b>, 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.</p> <p><b>Keep out of reach of children.</b></p> <p><b>Overdose warning:</b> 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.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>• do not use more than directed (see Overdose warning)</li> <li>• drink a full glass of water with each dose</li> <li>• adults and children 12 years and over: take 2 caplets every 6 hours; do not take more than 8 caplets in 24 hours</li> <li>• children under 12 years: ask a doctor</li> </ul> <p><b>Other information</b> • store between 20°-25°C (68°-77°F)</p> <p><b>Inactive ingredients</b> colloidal silicon dioxide, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone K30, pregelatinized starch, stearic acid, talc</p> <p><b>Questions or comments?</b> Call toll-free 1-877-507-6516 (M-F 8AM-4:30PM CST)</p>	<p>Compare to the Active Ingredients in Excedrin® Extra Strength**</p> <p><b>Extra Strength Headache</b></p> <p><b>Acetaminophen 250 mg</b> Pain Reliever</p> <p><b>Aspirin (NSAID) 250 mg Pain Reliever</b></p> <p><b>Caffeine 65 mg Pain Reliever Aid</b></p> <p><b>50 Caplets</b></p> <p>ACTUAL SIZE</p> 	<p><b>Drug Facts</b></p> <table border="1"> <thead> <tr> <th>Active ingredients (in each caplet)</th> <th>Purposes</th> </tr> </thead> <tbody> <tr> <td>Acetaminophen 250 mg</td> <td>Pain reliever</td> </tr> <tr> <td>Aspirin 250 mg (NSAID)*</td> <td>Pain reliever</td> </tr> <tr> <td>Caffeine 65 mg</td> <td>Pain reliever aid</td> </tr> </tbody> </table> <p>*nonsteroidal anti-inflammatory drug</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>• temporarily relieves minor aches and pains due to:</li> <li>• headache • a cold • arthritis</li> <li>• muscular aches • sinusitis • toothache</li> <li>• premenstrual and menstrual cramps</li> </ul> <p><b>Warnings</b></p> <p><b>Reye's syndrome:</b> 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.</p> <p><b>Allergy alert:</b> Aspirin may cause a severe allergic reaction, which may include:</p> <ul style="list-style-type: none"> <li>• hives • facial swelling</li> <li>• asthma (wheezing) • shock</li> </ul> <p><b>Allergy alert:</b> Acetaminophen may cause severe skin reactions. Symptoms may include:</p> <ul style="list-style-type: none"> <li>• skin reddening</li> <li>• blisters • rash</li> </ul> <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p><b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take:</p> <ul style="list-style-type: none"> <li>• more than 8 caplets in 24 hours, which is the maximum daily amount</li> <li>• with other drugs containing acetaminophen</li> <li>• 3 or more alcoholic drinks every day while using this product</li> </ul> <p><b>Stomach bleeding warning:</b> This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:</p> <ul style="list-style-type: none"> <li>• are age 60 or older</li> <li>• have had stomach ulcers or bleeding problems</li> </ul>	Active ingredients (in each caplet)	Purposes	Acetaminophen 250 mg	Pain reliever	Aspirin 250 mg (NSAID)*	Pain reliever	Caffeine 65 mg	Pain reliever aid	<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>• take a blood thinning (anticoagulant) or steroid drug</li> <li>• take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)</li> <li>• have 3 or more alcoholic drinks every day while using this product</li> <li>• take more or for a longer time than directed</li> </ul> <p><b>Caffeine warning:</b> 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.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>• if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer</li> <li>• with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> </ul> <p><b>Ask a doctor before use if</b></p> <ul style="list-style-type: none"> <li>• you have liver disease</li> <li>• stomach bleeding warning applies to you</li> <li>• you have a history of stomach problems, such as heartburn</li> <li>• you have high blood pressure, heart disease, liver cirrhosis, or kidney disease</li> <li>• you are taking a diuretic</li> <li>• you have asthma</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are taking</b></p> <ul style="list-style-type: none"> <li>• any other drug containing an NSAID (prescription or nonprescription)</li> <li>• a prescription drug for diabetes, gout, or arthritis</li> <li>• any other drug or are under a doctor's care for any serious condition</li> <li>• a blood thinning (anticoagulant) or steroid drug</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>• an allergic reaction occurs. 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Active ingredients (in each caplet)	Purposes										
Acetaminophen 250 mg	Pain reliever										
Aspirin 250 mg (NSAID)*	Pain reliever										
Caffeine 65 mg	Pain reliever aid										

## PDP (CK)

# TEMPORARILY RELIEVES HEADACHES

Compare to the active ingredients in **Excedrin® Extra Strength\***

**CIRCLE K™**

**extra strength headache**

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

[caplet image]

actual size

**50 caplets**

<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>does not get better</li> <li>ringing in the ears or loss of hearing occurs</li> <li>painful area is red or swollen</li> <li>pain gets worse or lasts for more than 10 days</li> <li>fever gets worse or lasts for more than 3 days</li> <li>any new symptoms appear</li> </ul> <p>These could be signs of a serious condition.</p> <p><b>If pregnant or breast-feeding</b>, 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.</p> <p><b>Keep out of reach of children.</b> 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.</p> <p><b>Directions</b> • do not use more than directed • drink a full glass of water with each dose</p> <p><b>adults and children (12 years and over)</b> take 2 caplets every 6 hours as needed; not more than 8 caplets in 24 hours</p> <p><b>children under 12 years</b> ask a doctor</p> <p><b>Other information</b> • 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</p> <p><b>Inactive ingredients</b> colloidal silicon dioxide, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone K30, pregelatinized starch, stearic acid, talc talc</p> <p><b>Questions or comments?</b> Call toll-free 1-877-507-6516 (M-F 8AM-4:30PM CST)</p>	<p><b>TEMPORARILY RELIEVES HEADACHES</b></p> <p>Compare to the active ingredients in <b>Excedrin® Extra Strength*</b></p>  <p><b>Acetaminophen 250 mg, Pain Reliever Aspirin (NSAID) 250 mg, Pain Reliever Caffeine 65 mg, Pain Reliever Aid</b></p> <p>actual size</p> <p><b>50 caplets</b></p>	<p><b>Drug Facts</b></p> <p><b>Active ingredients (in each caplet) Purposes</b></p> <p>Acetaminophen 250 mg.....Pain reliever Aspirin (NSAID)* 250 mg.....Pain reliever Caffeine 65 mg.....Pain reliever aid *nonsteroidal anti-inflammatory drug</p> <p><b>Uses</b> temporarily relieves minor aches and pains due to: • headache • a cold • arthritis • muscular aches • toothache • premenstrual &amp; menstrual cramps</p> <p><b>Warnings</b></p> <p><b>Reye's syndrome:</b> Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. 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<b>EXTRA STRENGTH HEADACHE, CIRCLE K</b>			
acetaminophen/aspirin/caffeine tablet tablet			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66715-5506(NDC:68210-4094)
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)		ASPIRIN	250 mg
<b>CAFFEINE</b> (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)		CAFFEINE	65 mg

<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg		
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>		<b>Strength</b>		
TALC (UNII: 7SEV7J4R1U)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)				
POVIDONE K30 (UNII: U725QWY32X)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
STARCH, CORN (UNII: O8232NY3SJ)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
<b>Product Characteristics</b>				
<b>Color</b>	white (white to off-white with specs)	<b>Score</b>	no score	
<b>Shape</b>	OVAL (capsule-shaped biconvex)	<b>Size</b>	18mm	
<b>Flavor</b>		<b>Imprint Code</b>	S53	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:66715-5506-4	1 in 1 CARTON	09/24/2021	
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
<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>	
OTC Monograph Drug	M013	09/24/2021		

<b>EXTRA STRENGTH HEADACHE</b>			
acetaminophen/aspirin/caffeine tablet tablet			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66715-6922(NDC:68210-0107)
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>

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

### Inactive Ingredients

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

### Product Characteristics

<b>Color</b>	white (white to off-white with specs)	<b>Score</b>	no score
<b>Shape</b>	OVAL (capsule-shaped biconvex)	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	S53
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66715-6922-4	1 in 1 CARTON	09/24/2021	
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
OTC Monograph Drug	M013	09/24/2021	

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

Revised: 12/2023

Lil' Drug Store Products, Inc.