

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

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

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>Drug Facts (continued)</p> <ul style="list-style-type: none"> • 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 <p>These could be signs of a serious condition.</p> <p>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.</p> <p>Keep out of reach of children.</p> <p>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.</p> <p>Directions</p> <ul style="list-style-type: none"> • 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 <p>Other information • store between 20°-25°C (68°-77°F)</p> <p>Inactive ingredients colloidal silicon dioxide, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone K30, pregelatinized starch, stearic acid, talc</p> <p>Questions or comments? 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>Extra Strength Headache</p> <p>Acetaminophen 250 mg Pain Reliever</p> <p>Aspirin (NSAID) 250 mg Pain Reliever</p> <p>Caffeine 65 mg Pain Reliever Aid</p> <p></p> <p>ACTUAL SIZE</p> <p>50 Caplets</p> <p></p> | <p>Drug Facts</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>Uses • temporarily relieves minor aches and pains due to:</p> <ul style="list-style-type: none"> • headache • a cold • arthritis • muscular aches • sinusitis • toothache • premenstrual and menstrual cramps <p>Warnings</p> <p>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.</p> <p>Allergy alert: Aspirin may cause a severe allergic reaction, which may include: • hives • facial swelling • asthma (wheezing) • shock</p> <p>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.</p> <p>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</p> <p>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</p> | Active ingredients (in each caplet) | Purposes | Acetaminophen 250 mg | Pain reliever | Aspirin 250 mg (NSAID)* | Pain reliever | Caffeine 65 mg | Pain reliever aid | <p>Drug Facts (continued)</p> <ul style="list-style-type: none"> • 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 <p>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.</p> <p>Do not use</p> <ul style="list-style-type: none"> • 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. <p>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</p> <ul style="list-style-type: none"> • you are taking a diuretic • you have asthma <p>Ask a doctor or pharmacist before use if you are taking</p> <ul style="list-style-type: none"> • 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 <p>Stop use and ask a doctor if • an allergic reaction occurs. Seek medical help right away.</p> |
|--|---|--|-------------------------------------|----------|----------------------|---------------|-------------------------|---------------|----------------|-------------------|---|
| 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>Drug Facts (continued)</p> <ul style="list-style-type: none"> 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 <p>These could be signs of a serious condition.</p> <p>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.</p> <p>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.</p> <p>Directions • do not use more than directed • drink a full glass of water with each dose</p> <p>adults and children (12 years and over) take 2 caplets every 6 hours as needed; not more than 8 caplets in 24 hours</p> <p>children under 12 years ask a doctor</p> <p>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</p> <p>Inactive ingredients colloidal silicon dioxide, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone K30, pregelatinized starch, stearic acid, talc</p> <p>Questions or comments? Call toll-free 1-877-507-6516 (M-F 8AM-4:30PM CST)</p> | <p>TEMPORARILY RELIEVES HEADACHES</p> <p>Compare to the active ingredients in Excedrin® Extra Strength*</p>  <p>Acetaminophen 250 mg, Pain Reliever Aspirin (NSAID) 250 mg, Pain Reliever Caffeine 65 mg, Pain Reliever Aid</p> <p>actual size</p> <p>50 caplets</p> | <p>Drug Facts</p> <p>Active ingredients (in each caplet) Purposes</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>Uses temporarily relieves minor aches and pains due to: • headache • a cold • arthritis • muscular aches • toothache • premenstrual & menstrual cramps</p> <p>Warnings</p> <p>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.</p> <p>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.</p> <p>Allergy alert: Aspirin (NSAIDs) may cause a severe allergic reaction, which may include: • hives • facial swelling • asthma (wheezing) • shock</p> <p>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</p> <p>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</p> | <p>Drug Facts (continued)</p> <ul style="list-style-type: none"> 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 <p>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.</p> <p>Do not use</p> <ul style="list-style-type: none"> 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. <p>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</p> <p>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</p> <p>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</p> |
|---|--|---|--|

| EXTRA STRENGTH HEADACHE, CIRCLE K | | | |
|---|----------------|---------------------------|--------------------------------|
| acetaminophen/aspirin/caffeine tablet tablet | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:66715-5506(NDC:68210-4094) |
| Route of Administration | ORAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | | ASPIRIN | 250 mg |
| CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E) | | CAFFEINE | 65 mg |

| | | | | |
|---|---|--|-----------------------------|---------------------------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 250 mg | | |
| Inactive Ingredients | | | | |
| Ingredient Name | | Strength | | |
| 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) | | | | |
| Product Characteristics | | | | |
| Color | white (white to off-white with specs) | Score | no score | |
| Shape | OVAL (capsule-shaped biconvex) | Size | 18mm | |
| Flavor | | Imprint Code | S53 | |
| Contains | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:66715-5506-4 | 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 | | |

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

| | | |
|---|---------------|--------|
| ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN | 250 mg |
| CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E) | CAFFEINE | 65 mg |
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 250 mg |

Inactive Ingredients

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

Product Characteristics

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

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.