

HEADACHE RELIEF EXTRA STRENGTH- acetaminophen, aspirin, caffeine tablet, film coated

Walgreen Company

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Walgreens 44-159B Delisted

Active ingredients (in each tablet)

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:
 - toothache
 - arthritis
 - a cold
 - headache
 - muscular aches
 - 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:

- hives
- shock
- facial swelling
- 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
- 3 or more alcoholic drinks every day while using this product
- with other drugs containing acetaminophen

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 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.
- 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
- have bloody or black stools
- vomit blood
- have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- redness or swelling is present
- 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 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 accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 tablets every 6 hours
 - do not take more than 8 tablets in 24 hours
- children under 12 years: ask a doctor

Other information

- store at 25°C (77°F); excursions permitted between 15°C-30°C (59°F-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

Questions or comments?

1-800-426-9391

Principal Display Panel

Walgreens

Compare to Excedrin® Extra
Strength active ingredients††

NDC 0363-0159-15

Headache Relief

ACETAMINOPHEN / ASPIRIN (NSAID) / PAIN RELIEVER
CAFFEINE / PAIN RELIEVER AID

EXTRA STRENGTH

TABLETS

50 ANALGESIC
TABLETS

ACTUAL SIZE

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

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DEERFIELD, IL 60015 walgreens.com ©2018 Walgreen Co.

Walgreens Pharmacist Recommended

Walgreens Pharmacist Survey

††This product is not manufactured or distributed by
Novartis AG, owner of the registered trademark
Excedrin® Extra Strength.

50844 ORG041815915

ORG0818-F

Drug Facts (continued)

- 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:
 - 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
 - pain gets worse or lasts for more than 10 days
 - fever gets worse or lasts for more than 3 days
 - redness or swelling is present
 - 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 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 accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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No Print Area
Lot no. & Exp. Date

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

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ITEM 692841 W00000-0000-0

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Drug Facts (continued)

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you are 60 or older, if you have had stomach ulcers or bleeding problems, if you take a blood thinning (anticoagulant) or steroid drug, or if you 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 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 ■ you have a history of stomach problems, such as heartburn ■ you are taking a diuretic ■ you have high blood pressure, heart disease, liver cirrhosis, or kidney disease ■ you have asthma

Ask a doctor or pharmacist before use if you are ■ taking a prescription drug for diabetes, gout, or arthritis

Drug Facts (continued)

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, croscopolone, hydroxypropyl cellulose, microcrystalline cellulose, polyvinylpyrrolidone, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments? 1-800-426-9391

Walgreens Pharmacist Recommended
Use the green Pharmacist Recommended logo to help you find the right product for your needs.
Novartis AG owner of the registered trademark Xcedrin® Extra Strength. 50844 ORG041815915

B-2201-159B-15-H
ORG041815915

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Drug Facts

Active ingredients (in each tablet)

- 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:
 - toothache
 - headache
 - a cold
 - menstrual and menstrual cramps
 - arthritis
 - muscular aches

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Allergy alert: Aspirin may cause a severe allergic reaction, which may include: ■ hives ■ shock ■ facial swelling ■ asthma (wheezing)

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ rash ■ skin redness ■ 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 ■ 3 or more alcoholic drinks every day while using this product ■ with other drugs containing acetaminophen

Walgreens

Compare to Xcedrin® Extra Strength active ingredients!

NDC 0363-0159-15

Headache Relief

ACETAMINOPHEN / ASPIRIN (NSAID) / PAIN RELIEVER
CAFFEINE / PAIN RELIEVER AID

EXTRA STRENGTH TABLETS

50 ANALGESIC TABLETS



ACTUAL SIZE

Walgreens 44-159B

HEADACHE RELIEF EXTRA STRENGTH

acetaminophen, aspirin, caffeine tablet, film coated

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0363-0159 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | 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 |
|---|----------|
| STARCH, CORN (UNII: O8232NY3SJ) | |
| CROSPROVIDONE (UNII: 2S7830E561) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | white | Score | no score |
| Shape | ROUND | Size | 11mm |
| Flavor | | Imprint Code | 44;159 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0363-0159-15 | 1 in 1 CARTON | 11/17/1992 | 04/28/2023 |
| 1 | | 50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| 2 | NDC:0363-0159-12 | 1 in 1 CARTON | 11/17/1992 | 04/28/2023 |
| 2 | | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| 3 | NDC:0363-0159-29 | 1 in 1 CARTON | 11/17/1992 | 07/28/2017 |
| 3 | | 150 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 not final | part343 | 11/17/1992 | 04/28/2023 |

Labeler - Walgreen Company (008965063)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 038154464 | pack(0363-0159) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. | | 832867837 | manufacture(0363-0159) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. | | 832867894 | manufacture(0363-0159) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 967626305 | pack(0363-0159) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. | | 117025878 | manufacture(0363-0159) |

Revised: 10/2022

Walgreen Company