

LEADER MIGRAINE RELIEF- acetaminophen, aspirin, caffeine tablet, film coated

Cardinal Health 110, LLC. dba Leader

Cardinal Health Migraine Relief Drug Facts

Active ingredients (in each tablet)

Acetaminophen 250 mg

Aspirin 250 mg (NSAID*)

Caffeine 65 mg

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever

Pain reliever aid

Use

- treats migraine

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: 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: 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 2 gels 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

Medication overuse headache warning: Headaches may worsen if this product is used for 10 or more days per month.

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 severe 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 never had migraines diagnosed by a health professional
- you have a headache that is different from your usual migraines
- you have the worst headache of your life
- you have fever and stiff neck
- you have headaches beginning after or caused by head injury, exertion, coughing or bending
- you experienced your first headache after the age of 50
- you have daily headaches
- you have a migraine so severe as to require bed rest
- 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
- you have problems or serious side effects from taking pain relievers or fever

- reducers
- you have vomiting with migraine headache

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for:
- diabetes
- gout
- arthritis
- under a doctor's care for any serious condition
- taking any other drug
- taking any other product that contains aspirin, acetaminophen, or any other pain reliever/fever reducer

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
- your migraine is not relieved or worsens after first dose
- new or unexpected symptoms occur
- ringing in the ears or loss of hearing occurs

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.

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**
- adults: take 2 gels with a glass of water
- if symptoms persist or worsen, ask your doctor
- do not take more than 2 gels in 24 hours, unless directed by a doctor
- under 18 years of age: as a doctor

Other information

- store at 20°-25°C (68°-77°F)
- close cap tightly after use
- read all product information before using. Keep this box for important information.

Inactive ingredients

black iron oxide, carnauba wax, crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, gelatin, glycerin, hypromellose, maltitol solution, medium-chain triglycerides, microcrystalline cellulose, pharmaceutical ink, polyvinyl acetate phthalate, povidone, pregelatinized starch, propylene glycol, stearic acid, titanium dioxide

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

LEADER™

Migraine Relief

Acetaminophen | Aspirin (NSAID) | Caffeine Tablets

Pain Reliever / Pain Reliever Aid

COMPARE TO EXCEDRIN® MIGRAINE active ingredients

80 GELTABS**

**Gelatin-Coated Tablets

Actual Size

100% Money Back Guarantee

NDC 70000-0611-1

LEADER[™]

Migraine Relief

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Pain Reliever / Pain Reliever Aid

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**Gelatin-Coated Tablets



Actual Size

COMPARE TO
EXCEDRIN[®]
MIGRAINE
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100% Money
Back Guarantee

22527 E9 C1



This product is not manufactured or distributed by SK Consumer Healthcare, distributor of Excedrin[®] Migraine.

Drug Facts

Active Ingredients (in each geltab) Purposes

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

*nonsteroidal anti-inflammatory drug

Use ■ treats migraine

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, vomiting, or vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin redness ■ blisters ■ rash
- skin reactions occur, stop use and seek medical help right away.

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

- hives ■ facial swelling ■ asthma (wheezing) ■ shock
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Drug Facts (continued)

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Drug Facts (continued)

Stop use and ask a doctor if

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- if symptoms persist or worsen, ask your doctor
- do not take more than 2 geltabs in 24 hours, unless directed by a doctor
- under 18 years of age: ask a doctor

Other Information

- store at 20°-25°C (68°-77°F) ■ close cap tightly after use
- read all product information before using. Keep this box for important information.

Inactive ingredients black iron oxide, carnauba wax, croscopolone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, gelatin, glycerin, hypromellose, methylcellulose, medium-chain triglycerides, microcrystalline cellulose, pharmaceutical ink, polyvinyl acetate phthalate, povidone, pregelatinized starch, propylene glycol, stearic acid, titanium dioxide

Questions or comments? 1-800-719-9260

Return to place of purchase if not satisfied.

ALL LEADER[™] Brand Products Have A 100% Money Back Guarantee

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DISTRIBUTED BY: CARDINAL HEALTH
DUBLIN, OHIO 43017
www.myexcedrin.com 1-800-330-8315

KEEP BOX FOR REFERENCE
DO NOT USE IF PRINTED FOLLOWS UNDER CAP
IS BROKEN OR MISSING

LEADER MIGRAINE RELIEF

acetaminophen, aspirin, caffeine tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70000-0611 |
| 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 |
|---|----------|
| FERROSO FERRIC OXIDE (UNII: XM0M87F357) | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| CROSPVIDONE (UNII: 2S7830E561) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| GELATIN, UNSPECIFIED (UNII: 2G86QN327L) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MALTITOL (UNII: D65DG142WK) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|--------------|---------------------|----------|
| Color | GREEN, WHITE | Score | no score |
| Shape | ROUND | Size | 13mm |
| Flavor | | Imprint Code | M |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70000-0611-1 | 1 in 1 CARTON | 08/08/2022 | |
| 1 | | 80 in 1 BOTTLE; Type 0: Not a Combination | | |

| Product | | | |
|------------------------------|--|----------------------|--------------------|
| Marketing Information | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| ANDA | ANDA075794 | 08/08/2022 | |

Labeler - Cardinal Health 110, LLC. dba Leader (063997360)

Revised: 8/2022

Cardinal Health 110, LLC. dba Leader