

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 caplet)

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 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: 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 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 your 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 caplets with a glass of water
- if symptoms persist or worsen, ask your doctor
- do not take more than 2 caplets 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

carnauba wax, crospovidone, FD&C blue #1 aluminum lake, hypromellose, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, saccharin sodium, stearic acid, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

LEADER™

Migraine Relief

Acetaminophen | Aspirin (NSAID) | Caffeine Tablets

Pain Reliever / Pain Reliever Aid

COMPARE TO EXCEDRIN® MIGRAINE

active ingredients

24 COATED CAPLETS**

**Capsule-Shaped Tablets

Actual Size

100% Money Back Guarantee

37462 E9 C13



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

Drug Facts

Active ingredients (in each caplet) Acetaminophen 250 mg, Aspirin 250 mg (NSAID), Caffeine 65 mg

Purpose Pain reliever

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.

Symptoms may include: skin redness, blisters, rash, itchy skin, tenderness, sore, and seek medical help right away.

Other warnings: Aspirin may cause a severe allergic reaction which may include: hives, facial swelling, asthma, wheezing, shock, low blood pressure, or difficulty breathing. Severe liver damage may occur if you take more than 2 caplets in 24 hours, which is the maximum daily amount, with other drugs containing acetaminophen.

Stomach bleeding warning: The 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 aspirin or other nonsteroidal anti-inflammatory drugs, aspirin, or other drugs, or have 3 or more alcoholic drinks per day while using this product.

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

Caffeine warning: The amount of caffeine in 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 heart beat.

Drug Facts (continued)

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 ever had migraine diagnosed by a health professional, you have headache facts different from your usual headaches, you have the worst headache of your life, you have fever and stiff neck, you have headaches beginning after you received your first heart transplant, you have dizziness, you experience your first headache after the age of 50, you have dizziness, you have a migraine so severe as to require bed rest, you have an asthma, stomach bleeding warning applies to you, you have a history of stomach problems, such as heartburn, you have high blood pressure, heart disease, low cholesterol, or kidney disease, you are taking a diuretic, you have asthma, you have problems or serious side effects from taking pain relievers/fever reducers, you have something with you making a 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: heartburn, 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 worsening symptoms occur, ringing in the ears or loss of hearing occurs.

If pregnant or breast-feeding, ask a health professional for use. It is especially important 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). Usual medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions (continued)

Other information Store at 20°-25°C (68°-77°F). Do not use if the caplet is broken or missing. Do not use if the caplet is broken or missing. Do not use if the caplet is broken or missing.

Contains Do not use more than directed. Adults: take 2 caplets with a glass of water. If symptoms persist or worsen, ask your doctor. Do not take more than 2 caplets in 24 hours. Do not use if the caplet is broken or missing. Do not use if the caplet is broken or missing.

Warnings (continued)

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Directions (continued)

DO NOT USE IF PRINTED POLYMER CAPS ARE BROKEN OR MISSING

KEEP BOX FOR REFERENCE

ACTUAL SIZE



Actual Size

LEADERTM

NDC 70000-0247-1

Migraine Relief

Acetaminophen | Aspirin (NSAID) | Caffeine Tablets
Pain Reliever / Pain Reliever Aid

COMPARE TO EXCEDRIN[®] MIGRAINE active ingredients*

24 COATED CAPLETS[™]
**Capsule-Shaped Tablets

100% Money Back Guarantee

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0247
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	L374
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0247-1	1 in 1 CARTON	02/16/2017	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70000-0247-2	1 in 1 CARTON	02/16/2017	
2		100 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	02/16/2017	

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

Revised: 3/2023

Cardinal Health 110, LLC. dba Leader