

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

**Cardinal Health 110, LLC. dba Leader**

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**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

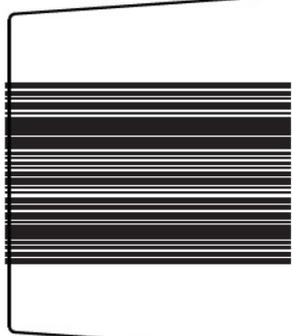
COMPARE TO EXCEDRIN® MIGRAINE RELIEF active ingredients

100 COATED CAPLETS\*\*

\*\*Capsule-Shaped Tablets

Actual Size

100% Money Back Guarantee



NDC 70000-0247-2



# Migraine Relief

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

**100 COATED CAPLETS\*\***  
\*\*Capsule-Shaped Tablets



Actual Size

**COMPARE TO EXCEDRIN<sup>®</sup> MIGRAINE RELIEF**  
active ingredients\*

100% Money Back Guarantee



37478 EQ C14

KEEP BOX FOR REFERENCE

DO NOT USE IF PRINTED FOLDLINE CAP IS BROKEN OR MISSING

100% Money Back Guarantee  
A LEADER Brand Product. Have A Return to place of purchase if not satis...

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DUBLIN, OHIO 43017  
www.leadertb.com  
1-800-720-6375

### Drug Facts

#### Active ingredients (in each caplet)

Acetaminophen 250 mg ..... Pain reliever  
Aspirin, 250 mg (NSAID)<sup>1</sup> ..... Pain reliever  
Caffeine 65 mg ..... Pain reliever aid  
<sup>1</sup>Nonsteroidal anti-inflammatory drug

#### Use

■ treats migraine

#### Warnings

**Reye's syndrome:** Children and teenagers who have or are receiving 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 if a skin reaction occurs, stop use and seek medical help right away. ■ rash ■ hives ■ skin redness ■ hives ■ hives ■ hives

#### Allergy alert:

Aspirin may cause a severe allergic reaction which may include: ■ facial swelling ■ hives ■ 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)

### Drug Facts (continued)

■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed

**Medication overdose 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 hiccups beginning after or caused by head injury, exertion, coughing or bending ■ 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 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

### Drug Facts (continued)

■ 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 or stomach bleeding: ■ hiccups ■ vomit blood ■ have bloody or black stools ■ 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

camphor wax, croscollon, FD&C blue #1 aluminum lake, hydroxyethylcellulose, microcrystalline cellulose, polyvinylpyrrolidone, pregelatinized starch, polyethylene glycol, saccharin sodium, stearic acid, titanium dioxide

#### Questions or comments?

1-800-719-6280

\*This product is not manufactured or distributed by GSK Consumer Health care, distributor of Excedrin<sup>®</sup> Migraine Relief.



<b>LEADER MIGRAINE RELIEF</b> acetaminophen, aspirin, caffeine tablet, film coated			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0247
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>CROSPVIDONE, UNSPECIFIED</b> (UNII: 2S7830E561)	
<b>FD&amp;C BLUE NO. 1 ALUMINUM LAKE</b> (UNII: J9EQA3S2JM)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	L374
<b>Contains</b>			

## 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	

Revised: 1/2026

Cardinal Health 110, LLC. dba Leader