

**TENSION HEADACHE- acetaminophen, caffeine tablet, film coated**  
**Cardinal Health 110, LLC. DBA Leader**

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**Leader 44-428**

***Active ingredients (in each caplet)***

Acetaminophen 500 mg  
(formulated with 65 mg caffeine)

***Purpose***

Pain reliever

***Uses***

- temporarily relieves minor aches and pains due to:
  - headache
  - muscular aches

***Warnings***

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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

- blisters
- rash
- skin reddening

If a skin reaction occurs, stop use and seek medical help right away.

**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**

- 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 are allergic to acetaminophen

**Ask a doctor before use if you have**

liver disease.

**Ask a doctor or pharmacist before use if you are**

taking the blood thinning drug warfarin.

**Stop use and ask a doctor if**

- new symptoms occur
- 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

These could be signs of a serious condition.

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

In case of accidental overdose, get medical help or contact a Poison Control Center 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**
- adults and children 12 years and over: take 2 caplets every 6 hours. Do not take more than 6 caplets 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, D&C red #27 aluminum lake, FD&C blue #2 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, sodium starch glycolate, stearic acid, talc, titanium dioxide

***Questions or comments?***

**1-800-426-9391**

***Principal Display Panel***

**LEADER™**

NDC 70000-0159-2

**Tension Headache**

**Acetaminophen, 500 mg**

Caffeine, 65 mg

Pain reliever

Aspirin-Free

**COMPARE TO  
EXCEDRIN®**

**TENSION  
HEADACHE**

**active ingredients\***

100% Money

Back Guarantee

**100** CAPLETS

Actual Size

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

\*This product is not manufactured or distributed by GSK Consumer Healthcare S.A., owner of the registered trademark Excedrin® Tension Headache.

50844 REV1119B42812

**CardinalHealth™**

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

[www.myleader.com](http://www.myleader.com) 1-800-200-6313

**Essential to Care™ since 1979**

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√ All LEADER™ Brand Products Have A

**100% Money Back Guarantee**

Return to place of purchase if not satisfied.



Leader 44-428

## TENSION HEADACHE

acetaminophen, caffeine tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0159
<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	500 mg
<b>CAFFEINE</b> (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSPROVIDONE</b> (UNII: 2S7830E561)	
<b>D&amp;C RED NO. 27 ALUMINUM LAKE</b> (UNII: ZK64F7XSTX)	
<b>FD&amp;C BLUE NO. 2 ALUMINUM LAKE</b> (UNII: 4AQJ3LG584)	
<b>FD&amp;C YELLOW NO. 6 ALUMINUM LAKE</b> (UNII: GYP6Z2JR6Q)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	44;428
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0159-1	1 in 1 CARTON	01/17/2007	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70000-0159-2	1 in 1 CARTON	01/17/2007	
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
OTC Monograph Drug	M013	01/17/2007	

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

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(70000-0159)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(70000-0159)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(70000-0159)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(70000-0159)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(70000-0159)

Revised: 6/2024

Cardinal Health 110, LLC. DBA Leader