

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

-----

**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

**100** CAPLETS

Actual Size

**COMPARE TO EXCEDRIN®**

**TENSION HEADACHE**

active ingredients\*

100% Money Back Guarantee

**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 1-800-200-6313

**Essential to Care™ since 1979**

©2021 Cardinal Health. CARDINAL HEALTH, the Cardinal Health  
LOGO, ESSENTIAL TO CARE, LEADER, and the Leader LOGO are  
trademarks or registered trademarks of Cardinal Health.

All other marks are the property of their respective owners.

All LEADER™ Brand Products Have A

**100% Money Back Guarantee**

Return to place of purchase if not satisfied.



## TENSION HEADACHE

acetaminophen, caffeine tablet, film coated

### Product Information

#### Product Type

HUMAN OTC DRUG

#### Item Code (Source)

NDC:70000-0159

#### Route of Administration

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>CROSPVIDONE</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</b> (UNII: H77VEI93A8)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I3O)	
<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.		832867894	manufacture(70000-0159)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	pack(70000-0159)

**Establishment**

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

Revised: 6/2023

Cardinal Health 110, LLC. DBA Leader