

**ACETAMINOPHEN EXTRA STRENGTH- acetaminophen tablet, coated**  
**Cardinal Health 110, LLC. DBA Leader**

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**Leader 44-519**

***Active ingredient (in each gelcap)***

Acetaminophen 500 mg

***Purpose***

Pain reliever/fever reducer

***Uses***

- temporarily relieves minor aches and pains due to:
  - minor pain of arthritis
  - headache
  - muscular aches
  - toothache
  - backache
  - the common cold
  - premenstrual and menstrual cramps
- temporarily reduces fever

***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:

- skin reddening
- blisters
- rash

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

***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 or any of the inactive ingredients in this product

**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**

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

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 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 gelcaps every 6 hours while symptoms last
  - do not take more than 6 gelcaps in 24 hours, unless directed by a doctor
  - do not take for more than 10 days unless directed by a doctor
- children under 12 years: ask a doctor

***Other information***

- see end flap for expiration date and lot number
- store at 25°C (77°F); excursions permitted between 15°C-30°C (59°F-86°F)
- avoid high humidity

***Inactive ingredients***

croscarmellose sodium, D&C red #33, FD&C blue #1, FD&C red #40, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, stearic acid, titanium dioxide

***Questions or comments?***

**1-800-426-9391**

***Principal Display Panel***

**LEADER™**

NDC 70000-0312-1

Extra Strength

**Acetaminophen**

Gelcaps, 500 mg | Pain Reliever / Fever Reducer

Aspirin-Free

**50 GELCAPS**

Actual Size

**COMPARE TO  
TYLENOL® EXTRA  
STRENGTH RAPID  
RELEASE GELS**

active ingredient\*

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  
Johnson & Johnson Corporation, owner of the registered  
trademark Tylenol® Extra Strength Rapid Release Gels.  
50844 REV0322B51915

**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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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.

no print / no varnish area  
lot no. & exp. date

CIN 5345608 REV. 9/22  
0 962951 13233 5  
TAMPER EVIDENT: DO NOT USE IF  
IMPRINTED SAFETY SEAL UNDER  
CAP IS BROKEN OR MISSING

KEEP OUTER PACKAGE  
FOR COMPLETE  
PRODUCT INFORMATION

Drug Facts

Active ingredient  
(in each gelcap)  
Acetaminophen 500 mg. ... Pain reliever/fever reducer

Purpose

Uses

Warnings

Compare to  
TYLENOL® EXTRA  
STRENGTH RAPID  
RELEASE GELS  
active ingredient\*

100% Money Back Guarantee

Extra Strength  
Acetaminophen

Gelcaps, 500 mg | Pain Reliever / Fever Reducer

Aspirin-Free

50 GELCAPS

Actual Size

CardinalHealth™

DISTRIBUTED BY CARDINAL HEALTH  
DUBLIN, OHIO 43007  
www.mylender.com 1-800-200-6313  
Essential to Care® Since 1979

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Drug Facts (continued)

hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, stearic acid, titanium dioxide

Questions or comments? 1-800-426-9391

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Tylenol® Extra Strength Rapid Release Gels. 50844 REV0322851915

Drug Facts (continued)

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  
■ pain gets worse or lasts more than 10 days  
■ fever gets worse or lasts more than 3 days  
■ new symptoms occur  
■ redness or swelling is present  
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 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 gelcaps every 6 hours while symptoms last  
■ do not take more than 6 gelcaps in 24 hours, unless directed by a doctor  
■ do not take for more than 10 days unless directed by a doctor  
■ children under 12 years: ask a doctor

Other information  
■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) ■ avoid high humidity  
■ see end flap for expiration date and lot number

Inactive Ingredients crosarmellose sodium, D&C red #33, FD&C blue #1, FD&C red #40, gelatin.

LEADER<sup>2</sup>

Extra Strength  
Acetaminophen

Gelcaps, 500 mg  
Pain Reliever / Fever Reducer

Leader 44-519

ACETAMINOPHEN EXTRA STRENGTH

acetaminophen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0312
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

## Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	blue, red	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	L;5
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0312-1	1 in 1 CARTON	05/10/2004	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70000-0312-2	1 in 1 CARTON	05/10/2004	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:70000-0312-3	1 in 1 CARTON	05/10/2004	06/21/2023
3		225 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	05/10/2004	

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

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	manufacture(70000-0312) , pack(70000-0312)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(70000-0312)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(70000-0312)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(70000-0312)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(70000-0312)

Revised: 6/2023

Cardinal Health 110, LLC. DBA Leader