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

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 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- 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™

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DUBLIN, OHIO 43017
www.myleader.com 1-800-200-6313
Essential to Care™ since 1979

All LEADER™ Brand
Products Have A
100%
Money Back
Guarantee

Return to place of

purchase if not satisfied.

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: 3WQ0SDW1A)	
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)