PAIN RELIEVER EXTRA STRENGTH- acetaminophen tablet
L.N.K. International, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Quality Plus 44-519

Active ingredient
(in each gelcap)

Acetaminophen 500 mg

Purpose

Pain reliever / fever reducer

Uses

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

Warnings

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 6 gelcaps (3,000 mg) in 24 hours. 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

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.

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.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. 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 take more than directed (see overdose warning)**
- 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: do not use this adult extra strength product in children under 12 years of age; this will provide more than the recommended dose (overdose) of acetaminophen and may cause liver damage

Other information

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

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?

Call 1-800-426-9391

Principal Display Panel

QUALITY PLUS **NDC 50844-519-02**

*Compare to the active ingredient in Extra Strength TYLENOL® Rapid Release Gels

EXTRA STRENGTH
Pain Reliever
Acetaminophen 500 mg

PAIN RELIEVER/FEVER REDUCER
NON-ASPIRIN

12 Rapid Release Gelcaps 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 McNeil Consumer Healthcare, owner of the registered trademark Extra Strength TYLENOL® Rapid Release Gels.

Distributed by **LNK INTERNATIONAL, INC.**
60 Arkay Drive, Hauppauge, NY 11788
USA 50844 REV0513D51902

Quality Plus 44-519

PAIN RELIEVER EXTRA STRENGTH

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50844-519
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 (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
SHELLAC (UNII: 46N107B71O)	

Product Characteristics

Color	RED, BLUE	**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:50844-519-15	1 in 1 CARTON	05/10/2004	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:50844-519-02	1 in 1 CARTON	05/10/2004	
2		12 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	05/10/2004	

Labeler - L.N.K. International, Inc. (038154464)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(50844-519)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	MANUFACTURE(50844-519) , PACK(50844-519)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(50844-519)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(50844-519)

Revised: 3/2020 L.N.K. International, Inc.