

**ACETAMINOPHEN EXTRA STRENGTH- acetaminophen tablet, coated
FOODHOLD U.S.A., LLC**

CareOne 44-519

Active ingredient (in each gelcap)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - toothache
 - muscular aches
 - the common cold
 - headache
 - backache
 - minor pain from arthritis
 - 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:

- blisters
- rash
- skin reddening

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.

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
- any new symptoms appear
- redness or swelling is present

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°C-30°C (59°F-86°F)
- avoid high humidity
- use by expiration date on package

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

CAREONE®

NDC 41520-919-20

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

Extra Strength

ACETAMINOPHEN

500 mg

Pain Reliever

Fever Reducer

Contains no aspirin

OUR PHARMACIST

Rx

RECOMMEND

225

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 Kenvue Inc., owner of the registered trademark Extra Strength Tylenol® Rapid Release Gels.

50844 REV0525B51920

DISTRIBUTED BY: ADUSA DISTRIBUTION, LLC
SALISBURY, NC 28147

For product questions or concerns,
contact us at 1-833-992-3872

Quality guaranteed or your money back.

CAREone® NDC 41520-919-20
 Compare to the active ingredient in Extra Strength Tylenol® Rapid Release Gels*

Extra Strength
ACETAMINOPHEN
 500 mg
 Pain Reliever
 Fever Reducer

Contains no aspirin

225 GELCAPS Actual Size

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

No Print / No Varnish Lot no. & Exp. date

Drug Facts
Active ingredient (in each gelcap) Acetaminophen 500 mg Pain reliever/fever reducer
Purpose Pain reliever/fever reducer
Uses ■ temporarily relieves minor aches and pains due to:
 ■ headache ■ the common cold
 ■ backache ■ minor pain from arthritis
 ■ toothache ■ muscular aches
 ■ 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.
Ask a doctor before use if you have liver disease.

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 50844 RE10525851920

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 SALISBURY, NC 28147
 For product questions or concerns, contact us at
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 Quality guaranteed
 or your money back.

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PEEL HERE FOR MORE DRUG FACTS

Drug Facts (continued)
 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
 ■ redness or swelling is present
 ■ any new symptoms appear
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.

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Questions or comments? 1-800-426-9391

STOP PEELING

Care one 44-519

ACETAMINOPHEN EXTRA STRENGTH			
acetaminophen tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-919
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
CROSCARMELOSE 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	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:41520-919-12	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/10/2004	
2	NDC:41520-919-20	225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/10/2004	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	05/10/2004	

Labeler - FOODHOLD U.S.A., LLC (809183973)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	manufacture(41520-919) , pack(41520-919)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(41520-919)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(41520-919)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(41520-919)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(41520-919)

Revised: 1/2026

FOODHOLD U.S.A., LLC