ACETAMINOPHEN EXTRA STRENGTH- acetaminophen tablet, coated
Sam's West Inc

Members Mark 44-519

Active ingredient (in each gelcap)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

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

- if you are allergic to acetaminophen or any of the inactive ingredients in this product
- 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
- new symptoms occur
- fever gets worse or lasts more than 3 days
- 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

- use by expiration date on package
- 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

Principal Display Panel

Compare to Extra Strength Tylenol®

Rapid Release Gels active ingredient*

NDC 68196-919-05

Member's Mark®
QUALITY GUARANTEED

extra strength

acetaminophen
pain reliever/fever reducer
gelcaps, 500 mg

- non-aspirin
- relieves minor aches & pains

actual size

400
Gelcaps

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 Extra Strength Tylenol® Rapid Release Gels.
50844 REV0322B51905

DISTRIBUTED BY: SAM'S WEST, INC., BENTONVILLE, AR 72716

100% MONEY BACK GUARANTEE
SUPERIOR QUALITY AND PERFORMANCE
We would like to hear from you with any comments or suggestions. In the continental U.S. or Canada, you can call us at 1-800-426-9391 from 8:30 a.m to 4:00 p.m. EST Monday-Friday.

Members Mark 44-519

ACETAMINOPHEN EXTRA STRENGTH

acetaminophen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68196-919
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
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	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:68196-919-05	400 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 - Sam's West Inc (051957769)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	manufacture(68196-919) , pack(68196-919)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(68196-919)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(68196-919)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(68196-919)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(68196-919)

Revised: 10/2023 Sam's West Inc