EXTRA STRENGTH ACETAMINOPHEN- acetaminophen capsule
Sam's West 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.

Pain Reliever

Active ingredient (in each caplet)

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. Severe liver damage may occur if you take:

- more than 8 caplets in 24 hours, which is the maximum daily amount
- 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 of 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 damamge. In case of overdose, get medical help or contact a Poison Control Center 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 caplets every 4 to 6 hours while symptoms last
  - do not take more than 8 caplets in 24 hours
  - 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 controlled room temperature 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

caster oil, hypromellose, povidone, sodium starch glycolate*, starch, stearic acid
*may contain this ingredient

PRODUCT PACKAGING

NDC 68196-175-14 **pain reliever**

SIMPLY RIGHT™
Health Care

extra strength
acetaminophen

acetaminophen caplets, 500 mg
pain reliever / fever reducer

Compare to Extra Strength Tylenol® active ingredient†

non-aspirin
relieves minor aches & pains

500 caplets

actual size

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

50844 REV1012A17514

Distributed by:
SAM'S West, Inc.
Bentonville, AR 72716

Simply Right 44-175

EXTRA STRENGTH ACETAMINOPHEN

acetaminophen capsule

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:68196-175
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (ACETAMINOPHEN)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES	
STEARIC ACID	
CASTOR OIL	
SODIUM STARCH GLYCOLATE TYPE A POTATO	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	44;175
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-175-13	250 in 1 BOTTLE, PLASTIC		
2	NDC:68196-175-14	500 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	04/02/1993	

Labeler - Sam's West Inc (051957769)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(68196-175)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(68196-175)

Revised: 2/2013 Sam's West Inc