EXTRA STRENGTH ACETAMINOPHEN- acetaminophen tablet
Spirit Pharmaceutical LLC

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.

EXTRA STRENGTH ACETAMINOPHEN

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
  - the common cold
  - headache
  - backache
  - minor pain of 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.
- 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.

Overdose warning

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) 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 6 hours while symptoms last ■ do not take more than 6 caplets in 24 hours, unless directed by a doctor ■ do not use for more than 10 days unless directed by a doctor
children under 12 years	ask a doctor

Other information

- **each caplet contains:** magnesium 0.43 mg
- store between 20-25°C (68-77°F)
- **do not use if carton is opened or inner Safety Seal is broken or missing**

Inactive ingredients

Hypermellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinylpyrrolidone, pregelatinized starch, stearic acid, talc, titanium dioxide

Questions or comments?

1-888-333-9792

DISTRIBUTED BY:
FAMILY DOLLAR SERVICES, INC.,
10401 MONROE RD,
MATTHEWS, NC 28105 USA

PRINCIPAL DISPLAY PANEL - ACETAMINOPHEN 500MG CARTON

FAMILYwellness™

COMPARE TO THE ACTIVE
INGREDIENT OF EXTRA
STRENGTH TYLENOL® CAPLETS*

100% SATISFACTION
OR YOUR MONEY BACK
GUARANTEED

Extra Strength
Acetaminophen
Pain Reliever/Fever Reducer
Contains No Aspirin

50 CAPLETS - 500 mg
ACTUAL SIZE

EXTRA STRENGTH ACETAMINOPHEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68210-0013
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**
HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	white	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	S500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0013-5	1 in 1 CARTON	08/12/2016	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68210-0013-1	1 in 1 CARTON	08/12/2016	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:68210-0013-2	1 in 1 CARTON	08/12/2016	
3		250 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:68210-0013-4	1 in 1 CARTON	02/12/2020	
4		24 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 not final	part343	08/12/2016	

Labeler - Spirit Pharmaceutical LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LTD		915664486	manufacture(68210-0013)

Revised: 2/2020 Spirit Pharmaceutical LLC