

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	<ul style="list-style-type: none">▪ 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

LOT:
EXP:



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

EXTRA STRENGTH

Acetaminophen

Pain Reliever/Fever Reducer
Contains No Aspirin

50 CAPLETS
500 mg each

FAMILYwellness™



FAMILYwellness™

EXTRA STRENGTH

Acetaminophen

Pain Reliever/Fever Reducer
Contains No Aspirin

50 CAPLETS
500 mg each

Drug Facts (continued)
Other information
● Contains 500 mg of acetaminophen per caplet.
● For information on other brands of acetaminophen, see the back of the package.
● Do not use if the seal is broken or missing.

Active Ingredients
Acetaminophen (N-(4-aminophenyl)acetamide), 500 mg per caplet.

Contains No Aspirin

DISTRIBUTED BY:
MIDWOOD BRANDS, LLC
10011 WINDHOE RD.
MARTINEZ, NC 28105

MADE IN INDIA. DRUGS 0816

NOT 100% SATISFIED?
Return package and unused product
for a full refund. No money back offer
alone for return (with receipt) or
exchange.

*This product is not manufactured or
distributed by McNeil Consumer
Healthcare, owner of the registered
trademark, Tylenol®.

**READ AND KEEP CARDS FOR COMPLETE
DIRECTIONS AND INFORMATION**

Drug Facts
Active ingredient
(in each caplet)
Acetaminophen 500 mg. *Some medicines have other
ingredients.

Uses
● Temporarily relieves minor aches and pains due to:
● the common cold
● headache
● toothache
● sore throat
● muscle aches
● menstrual cramps
● temporary relief of fever

Warnings
Liver warning: This product can cause liver damage.
● Do not take if you are taking other medicines that
contain acetaminophen. Do not take if you have
● taken more than 3,000 mg of acetaminophen in the last
● 24 hours.
● Do not use if the package contains acetaminophen.
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Directions
● Take 2 caplets every 6 hours
● with or without food.
● Do not take more than 6
● caplets in 24 hours, unless
● your doctor tells you to do so.
● Do not take for more than 10
● days unless directed by a doctor.
● See a doctor.

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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