

**ASSURED EXTRA STRENGTH ACETAMINOPHEN- acetaminophen tablet**  
**SPIRIT PHARMACEUTICALS 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.*

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**ASSURED™ 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)**

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adults and children 12 years and over	<ul style="list-style-type: none"><li>• take 2 caplets every 6 hours while symptoms last</li><li>• do not take more than 6 caplets in 24 hours, unless directed by a doctor</li><li>• do not use for more than 10 days unless directed by a doctor</li></ul>
children under 12 years	ask a doctor

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### 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  
GREENBRIER INTERNATIONAL, INC.  
500 VOLVO PARKWAY, CHESAPEAKE, VA 23320**

**PRINCIPAL DISPLAY PANEL - 500 mg Caplet Bottle**

**ASSURED™**

**Compare TO THE ACTIVE INGREDIENT IN**

# EXTRA STRENGTH TYLENOL® CAPLETS†

## EXTRA STRENGTH

### Acetaminophen

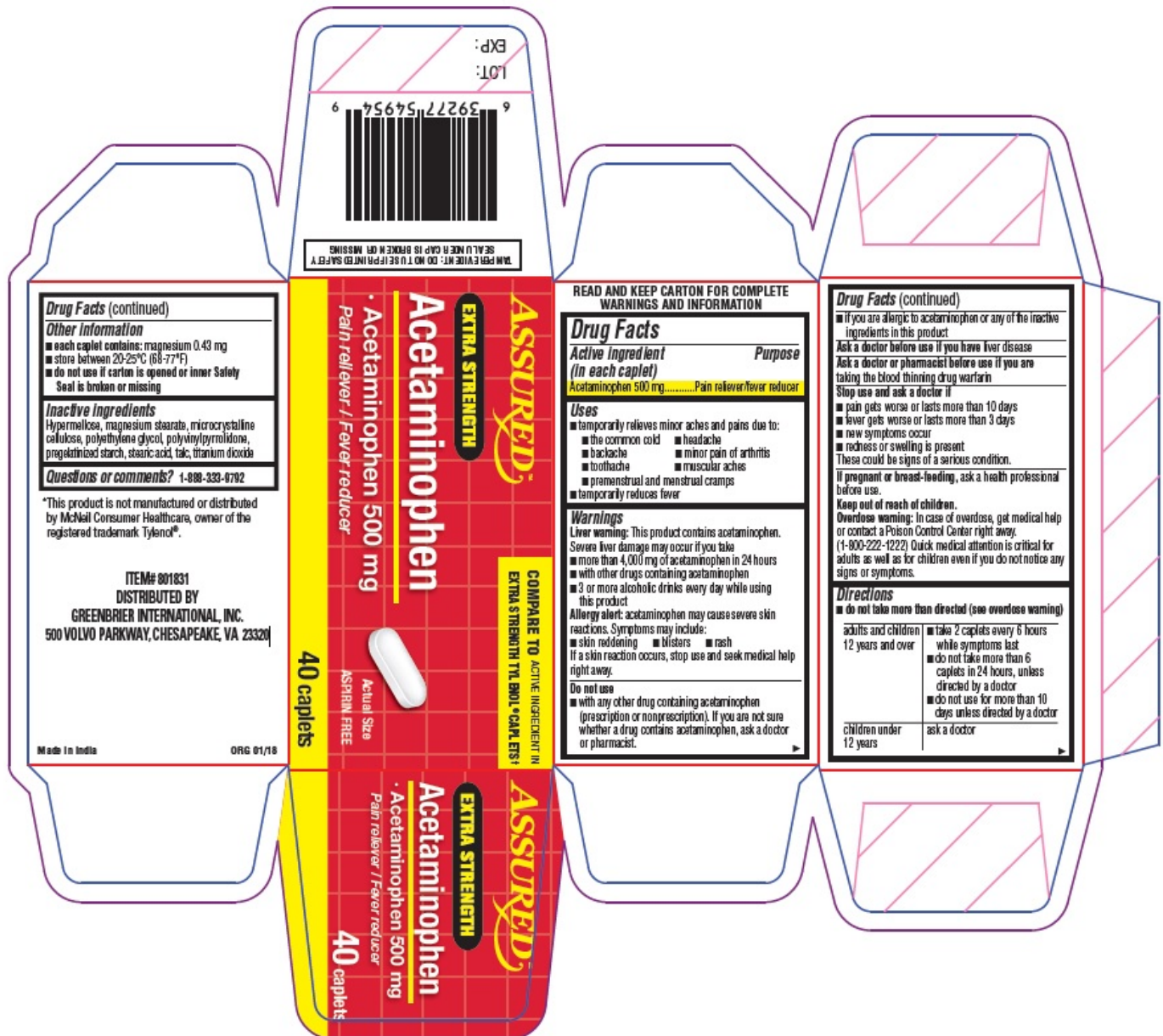
- Acetaminophen 500 mg

### Pain Reliever/ Fever reducer

Actual Size

ASPIRIN FREE

40 CAPLETS



## ASSURED EXTRA STRENGTH ACETAMINOPHEN

acetaminophen tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-3100
<b>Route of Administration</b>	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

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	S500
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-3100-4	1 in 1 CARTON	04/10/2018	
1		40 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	04/10/2018	

**Labeler** - SPIRIT PHARMACEUTICALS LLC (179621011)

### Establishment

Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LTD		915664486	manufacture(68210-3100)

