

**VALUMEDS EXTRA STRENGTH PAIN RELIEF- acetaminophen tablet**  
**SPIRIT PHARMACEUTICALS LLC**

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**VALUMEDS EXTRA STRENGTH PAIN RELIEF**

***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)

## **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

Spirit Pharmaceuticals, LLC

Ronkonkoma, NY 11779

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

**VALUMEDS**

**EXTRA STRENGTH**

**PAIN**

**RELIEF**

**ACETAMINOPHEN 500 mg**

**PAIN RELIVER/FEVER REDUCER**

**100 CAPLETS**

Compare to the active ingredient  
in Extra Strength Tylenol®\*

# EXTRA STRENGTH PAIN RELIEF

ACETAMINOPHEN 500 mg  
PAIN RELIEVER/  
FEVER REDUCER

100 CAPLETS

TAMPER EVIDENCE: SCHEMATIC USE & PRINTED  
SAFETY SEAL UNDER CAPLET BRIDGE ON MISSING

**Drug Facts**

**Active ingredient (in each caplet) Purpose**  
Acetaminophen 500 mg.....Pain reliever/fever reducer

**Uses**

- temporarily relieves minor aches and pains due to:
  - the common cold
  - headache
  - minor pain of arthritis
  - toothache
  - muscular aches
  - menstrual 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  
 ■ 5 or more alcoholic drinks every day while using this product

**Allergy alert:**  
 acetaminophen may cause severe skin reactions.  
 Symptoms may include: ■ skin redness ■ 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.

(continued under label)

Distributed By: Spirit Pharmaceuticals, LLC  
 Ronkonkoma, NY 11779    **ORIG 04/17**

ITEM# 201-01  
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Lot No: \_\_\_\_\_ Exp. Date: \_\_\_\_\_

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**Drug Facts (continued)**

**Ask a doctor before use if you have liver disease**  
 taking the blood thinning drug warfarin

**Ask a doctor or pharmacist before use if you are**  
 taking the blood thinning drug warfarin

**Stop use and ask a doctor if**

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- fever gets worse or lasts more than 3 days
- new symptoms occur
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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.**

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 Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

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

**Questions or comments? 1-888-333-9792**

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered Trademark Extra Strength Tylenol®

## VALUMEDS EXTRA STRENGTH PAIN RELIEF

acetaminophen tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-0130
<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)	

<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (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:68210-0130-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	05/15/2017	

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