

**EXTRA STRENGTH PAIN RELIEVER- acetaminophen, aspirin, and caffeine 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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**VALUMEDS EXTRA STRENGTH PAIN RELIEVER**

***Drug Facts***

<b><i>Active ingredient (in each caplet)</i></b>	<b><i>Purpose</i></b>
Acetaminophen 250 mg	Pain reliever
Aspirin 250 mg (NSAID) *	Pain reliever
Caffeine 65 mg	Pain reliever aid

\* nonsteroidal anti-inflammatory drug

**Uses**

temporarily relieves minor aches and pains due to:

- headache
- a cold
- arthritis
- muscular aches
- sinusitis
- toothache
- premenstrual & menstrual cramps

**Warnings**

**Reye's syndrome**

Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert**

Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

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.

**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

### **Stomach bleeding warning**

This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause stomach bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing an NSAID (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

### **Caffeine warning**

The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.

### **Do not use**

- if you have ever had an allergic reaction to aspirin or any other pain reliever/fever reducer
- 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 doctor before use if**

- you have liver disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis or kidney disease
- you are taking a diuretic
- high blood pressure
- you have asthma

### **Ask a doctor or pharmacist before use**

- any other drug containing an NSAID (prescription or nonprescription)
- a blood thinning (anticoagulant) or steroid drug
- a prescription drug for diabetes, gout, or arthritis
- any other drug, or are under a doctor's care for any serious condition

### **Stop use and ask doctor if**

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
- ringing in the ears or loss of hearing occurs
- painful area is red or swollen
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days

- any new symptoms appear

**If pregnant or breast-feeding** ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

### **Keep out of reach of children**

### **Overdose Warning**

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 use more than directed (**see Overdose Warning**)
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 caplets every 6 hours; not more than 8 caplets in 24 hours
- children under 12 years: ask a doctor

### **Other information**

- **Each caplet contains:** Magnesium 0.58 mg
- store at controlled room temperature 20° - 25° C (68° - 77° F)
- read all product information before using. Keep this box for important information

### **Inactive ingredients**

colloidal silicon dioxide, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, stearic acid, talc

### **Questions or comments**

**1-888-333-9792**

### **DISTRIBUTED BY**

**SPIRIT PHARMACEUTICALS, LLC.**

**RONKONKOMA, NY 11779**

**PRINCIPAL DISPLAY PANEL - 24 CAPLET BOTTLE CARTON**

**VALUMEDS™**

**Compare to the active ingredients in**

**EXCEDRIN® EXTRA STRENGTH\***

**EXTRA STRENGTH**

**PAIN RELIEVER**

**ACETAMINOPHEN, ASPIRIN (NSAID) AND CAFFEINE**

**PAIN RELIEVER/PAIN RELIEVER AID**

**24 CAPLETS**



# EXTRA STRENGTH PAIN RELIEVER

acetaminophen, aspirin, and caffeine tablet

**Drug Facts (continued)**  
 (NSAID), which may cause stomach bleeding. The chance is highest if you:
 

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing an NSAID (aspirin, ibuprofen, naproxen, or others)
- take 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

**Caution warning:** The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.

**Do not use:**

- if you have ever had an allergic reaction to aspirin or any other pain reliever/fever reducer
- 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 doctor before use if:**

- you have liver disease
- stomach bleeding warning applies to you
- you have any of the following conditions such as heartburn
  - heart disease, high blood pressure, heart disease, liver cirrhosis
  - kidney disease
  - you are taking a diuretic
  - high blood pressure
  - you have asthma

**Ask a doctor or pharmacist before use:**

- any other drug containing an NSAID (prescription or nonprescription)
- a blood thinning (anticoagulant) or steroid drug
- a prescription drug for diabetes, gout, or arthritis

**READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION**

**Drug Facts**

**Active ingredient (in each caplet)**  
 Acetaminophen 250 mg  
 Aspirin 250 mg (NSAID)  
 Caffeine 65 mg  
*"Nonsteroidal anti-inflammatory drug"*  
 Pain reliever aid  
 Pain reliever aid

**Purpose**  
 Pain reliever  
 Pain reliever aid

**Uses** Temporarily relieves minor aches and pains due to:
 

- headaches
- colds
- arthritis
- muscular aches
- rheumatoid arthritis
- toothache
- premenstrual & menstrual cramps

**Warnings**

- **Risks:** Aspirin may cause a severe allergic reaction which may reduce:
  - blood
  - liver
  - blood swelling
  - asthma (wheezing)
  - shock
- 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.
- **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
  - for more alcoholic drinks every day while using this product
- **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug.

**VALUMEDS**™

Compare to the active ingredients in EXCEDRIN® EXTRA STRENGTH®

## EXTRA STRENGTH PAIN RELIEVER

ACETAMINOPHEN, ASPIRIN (NSAID) AND CAFFEINE PAIN RELIEVER/PAIN RELIEVER AID

24 CAPLETS

**Drug Facts (continued)**  
 ■ any other drug, or are under a doctor's care for any serious condition

**Stop use and ask doctor if:**

- an allergic reaction occurs. Seek medical help right away.
- stomach bleeding or black stools occur
- rash, hives, or skin redness occur
- vomit, black or bloody stool, or black stools
- nosebleeds occur
- severe stomach pain that does not get better
- ringing in the ears or loss of hearing occurs
- painful area is red or swollen
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- any new symptoms appear

**If pregnant or breast-feeding** ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children**

**Overdose Warning:** In case of overdose, get medical help or attention as soon as possible. Call a poison control center or your doctor. If the patient is, or could be, a child or infant, you do not induce any signs or symptoms.

**Directions**

- do not use more than directed (**See Overdose Warning**)
- take 1 full glass of water with each dose
- adults and teenagers: 2 caplets 4 to 6 times per day not more than 8 caplets in 24 hours
- children under 12 years: ask a doctor

**Other information**

- Each caplet contains: Acetaminophen 0.250 g
- Store at controlled room temperature 20° - 25° C (68° - 77° F)

**Drug Facts (continued)**  
 ■ read all product information before using. Keep this box for important information

**Inactive ingredients**  
 calcium silicate, croscarmellose sodium, hydroxypropyl cellulose, hydroxypropyl methylcellulose, hypromellose, microcrystalline cellulose, polyethylene glycol 400, polyethylene glycol 6000, polyethylene glycol 8000, polyethylene glycol 1500, polyethylene glycol 200, polyethylene glycol 400, polyethylene glycol 600, polyethylene glycol 800, polyethylene glycol 1000, polyethylene glycol 1500, polyethylene glycol 2000, polyethylene glycol 4000, polyethylene glycol 6000, polyethylene glycol 8000, polyethylene glycol 10000, polyethylene glycol 15000, polyethylene glycol 20000, polyethylene glycol 40000, polyethylene glycol 60000, polyethylene glycol 80000, polyethylene glycol 100000, polyethylene glycol 150000, polyethylene glycol 200000, polyethylene glycol 400000, polyethylene glycol 600000, polyethylene glycol 800000, polyethylene glycol 1000000, polyethylene glycol 1500000, polyethylene glycol 2000000, polyethylene glycol 4000000, polyethylene glycol 6000000, polyethylene glycol 8000000, polyethylene glycol 10000000, polyethylene glycol 15000000, polyethylene glycol 20000000, polyethylene glycol 40000000, polyethylene glycol 60000000, polyethylene glycol 80000000, polyethylene glycol 100000000, polyethylene glycol 150000000, polyethylene glycol 200000000, polyethylene glycol 400000000, polyethylene glycol 600000000, polyethylene glycol 800000000, polyethylene glycol 1000000000, polyethylene glycol 1500000000, polyethylene glycol 2000000000, polyethylene glycol 4000000000, polyethylene glycol 6000000000, polyethylene glycol 8000000000, polyethylene glycol 10000000000, polyethylene glycol 15000000000, polyethylene glycol 20000000000

**Questions or comments? 1-888-353-8782**

This product is not manufactured or distributed by Abbott Consumer Health, Inc., owner of the registered trademark "Excedrin".

DISTRIBUTED BY  
 SPIRIT PHARMACEUTICALS, LLC  
 BIRMGHAM, AL 35209

017-0024

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

LOT:  
 EXP:  
 01402321160524116  
 017-0024

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-1700
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL (capsule shaped, biconvex tablets)	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	S53
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-1700-2	1 in 1 CARTON	04/10/2018	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part343	04/10/2018	

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

**Establishment**

Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LIMITED		915664486	manufacture(68210-1700)

Revised: 12/2019

SPIRIT PHARMACEUTICALS LLC