

**EXTRA STRENGHT HEADACHE RELIEF- acetaminophen, aspirin, caffeine 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.*

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**EXTRA STRENGTH HEADACHE RELIEF**

***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 an NSAID, which may cause severe 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 prescription or nonprescription NSAIDs (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 acetaminophen, 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
- you have asthma

### **Ask a doctor or pharmacist before use if you are taking**

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

### **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

These could be signs of a serious condition

**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. 1(800) 222-1222

### **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: MIDWOOD BRANDS, LLC  
10611 MONROE RD, MATTHEWS, NC 28105 USA

**PRINCIPAL DISPLAY PANEL - 100 Caplet Bottle Carton**

**FAMILYwellness™**

**COMPARE TO THE ACTIVE  
INGREDIENTS OF EXCEDRIN®  
EXTRA STRENGTH\***

**100% SATISFACTION**

LOT:  
EXP:

0 32251 23763 8



SKU 091144

**TEMPERATURE-SENSITIVE DO NOT USE IF PRINTED SAFETY  
TEXT CANNOT BE SEEN ON THE BOX**

COMPARE TO THE ACTIVE INGREDIENTS OF  
**EXCEDIN® EXTRA STRENGTH™**

**EXTRA STRENGTH**

# Headache Relief

Acetaminophen  
Aspirin (NSAID) and Caffeine  
Pain Reliever/Pain Reliever Aid



ACTUAL SIZE

100 CAPLETS

FAMILY **wellness™**



OTC network

#### Drug Facts (continued)

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. Use during earlier pregnancy may cause problems in the unborn child or complications during delivery.

**Keep use of headache relievers to a minimum.** Overuse can cause liver damage, kidney damage, and stomach ulcers. Call your doctor if you have any of the following symptoms:  
● dizziness or lightheadedness  
● ringing in ears or hearing problems  
● blurred vision or double vision  
● drowsiness  
● difficulty breathing  
● persistent or severe stomach pain  
● dark stools, black or tarry stools  
● vomiting or vomit with blood  
● persistent or severe headache  
● persistent or severe sore throat  
● persistent or severe nosebleed  
● persistent or severe swelling of the face, lips, or tongue  
● persistent or severe swelling of the hands or feet  
● persistent or severe swelling of the feet or ankles  
● persistent or severe swelling of the legs or arms  
● persistent or severe swelling of the arms or hands  
● persistent or severe swelling of the face, neck, or throat  
● persistent or severe swelling of the chest or back  
● persistent or severe swelling of the stomach or abdomen  
● persistent or severe swelling of the bladder or urinary tract  
● persistent or severe swelling of the penis or testicles  
● persistent or severe swelling of the vulva or vagina  
● persistent or severe swelling of the breasts or nipples  
● persistent or severe swelling of the breasts or underarms  
● persistent or severe swelling of the breasts or armpits  
● persistent or severe swelling of the breasts or groin  
● persistent or severe swelling of the breasts or buttocks  
● persistent or severe swelling of the breasts or thighs  
● persistent or severe swelling of the breasts or knees  
● persistent or severe swelling of the breasts or ankles  
● persistent or severe swelling of the breasts or feet  
● persistent or severe swelling of the breasts or toes  
● persistent or severe swelling of the breasts or fingers  
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**Warnings:** **Aspirin:** Do not use if you have had an allergic reaction to aspirin or any other drug containing aspirin. Do not use if you are taking any other drug containing aspirin. Do not use if you are taking any other drug containing acetaminophen. Do not use if you are taking any other drug containing caffeine. Do not use if you are taking any other drug containing ibuprofen. Do not use if you are taking any other drug containing naproxen. Do not use if you are taking any other drug containing celecoxib. Do not use if you are taking any other drug containing rofecoxib. Do not use if you are taking any other drug containing valdecoxib. Do not use if you are taking any other drug containing etoricoxib. Do not use if you are taking any other drug containing meloxicam. Do not use if you are taking any other drug containing nimesulide. Do not use if you are taking any other drug containing piroxicam. Do not use if you are taking any other drug containing tenoxicam. Do not use if you are taking any other drug containing tiarfenadine. Do not use if you are taking any other drug containing tiaprofenic acid. Do not use if you are taking any other drug containing valdecoxib. Do not use if you are taking any other drug containing etoricoxib. Do not use if you are taking any other drug containing meloxicam. Do not use if you are taking any other drug containing nimesulide. Do not use if you are taking any other drug containing piroxicam. Do not use if you are taking any other drug containing tenoxicam. Do not use if you are taking any other drug containing tiarfenadine. Do not use if you are taking any other drug containing tiaprofenic acid.

**Directions:** Adults and children 12 years and over: Take 2 caplets every 4 to 6 hours as needed. Do not exceed 6 caplets in 24 hours. Children under 12 years: Ask a doctor.

**Other information:** Each caplet contains: Acetaminophen 0.38 mg, Aspirin 250 mg, Caffeine 25 mg. Do not use if the product contains any of the following inactive ingredients: polyethylene glycol, croscellose, microcrystalline cellulose, hydroxypropyl methylcellulose, polyethylene glycol, pectin, croscellose, microcrystalline cellulose, hydroxypropyl methylcellulose, polyethylene glycol, starch, stearic acid, and sodium lauryl sulfate.

**Questions or comments:** 1-888-333-8782

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FAMILY **wellness™**

**EXTRA STRENGTH**

# Headache Relief

Acetaminophen  
Aspirin (NSAID) and Caffeine  
Pain Reliever/Pain Reliever Aid

100 CAPLETS

#### Drug Facts (continued)

**Caution:** The recommended dose of this product should not be exceeded. Do not use if you have had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer containing acetaminophen, aspirin or any other pain reliever/fever reducer. Do not use if you are taking any other drug containing acetaminophen, aspirin or any other pain reliever/fever reducer. Do not use if you are taking any other drug containing caffeine. Do not use if you are taking any other drug containing ibuprofen. Do not use if you are taking any other drug containing naproxen. Do not use if you are taking any other drug containing celecoxib. Do not use if you are taking any other drug containing rofecoxib. Do not use if you are taking any other drug containing valdecoxib. Do not use if you are taking any other drug containing etoricoxib. Do not use if you are taking any other drug containing meloxicam. Do not use if you are taking any other drug containing nimesulide. Do not use if you are taking any other drug containing piroxicam. Do not use if you are taking any other drug containing tenoxicam. Do not use if you are taking any other drug containing tiarfenadine. Do not use if you are taking any other drug containing tiaprofenic acid.

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GUARANTEED**

**Extra Strength  
Headache Relief  
Acetaminophen,  
Aspirin (NSAID) and Caffeine  
Pain Reliever/Pain Reliever Aid**

**100 CAPLETS**

## EXTRA STRENGHT HEADACHE RELIEF

acetaminophen, aspirin, caffeine tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0017
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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

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

### Product Characteristics

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0017-1	1 in 1 CARTON	08/18/2016	
1		100 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	08/18/2016	

**Labeler** - Spirit Pharmaceutical LLC (179621011)**Establishment**

Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LTD		915664486	manufacture(68210-0017)

Revised: 12/2019

Spirit Pharmaceutical LLC