

# TENSION HEADACHE RELIEF- acetaminophen and caffeine tablet

## SPIRIT PHARMACEUTICALS LLC

### TENSION HEADACHE RELIEF

#### *Drug Facts*

---

**Active ingredients (in each caplet)**

Acetaminophen 500 mg  
Caffeine 65 mg

---

**Purposes**

Pain reliever  
Pain reliever aid

#### **Uses**

- temporarily relieves minor aches and pains due to:
- headache
- muscular aches

#### **Warnings**

**Liver Warning:** This product contains acetaminophen. Severe liver damage may occur if you take.

- more than 6 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

**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.

**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, beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat.

#### **Do not use**

- if you are allergic to acetaminophen
- 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 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**

- any new symptoms occur
- painful area is red or swollen
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts for more than 3 days

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**

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**
- adults and children 12 years and over; take 2 caplets every 6 hours; not more than 6 caplets in 24 hours
- children under 12 years: ask a doctor

***Other information***

- store at 20°-25°C (68°-77°F)
- close cap tightly after use
- read all product information before using. Keep this box for important information.

***Inactive ingredients***

colloidal silicon dioxide, croscarmellose sodium, D&C Red#27, FD&C Blue#2, FD&C Yellow#6, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, purified water, stearic acid, talc, titanium dioxide

***Questions or comments?***

**1-888-333-9792**

**PRINCIPAL DISPLAY PANEL**

Tension Headache Relief  
Acetaminophen 500 mg, Caffeine 65 mg  
Pain Reliever  
15 Caplets



## TENSION HEADACHE RELIEF

acetaminophen and caffeine tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-4146
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
<b>CAFFEINE</b> (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>STARCH, PREGELATINIZED CORN</b> (UNII: O8232NY3SJ)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	18mm

<b>Flavor</b>		<b>Imprint Code</b>	S431
<b>Contains</b>			
<b>Packaging</b>			
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>
<b>1</b>	NDC:68210-4146-1	1 in 1 CARTON	04/28/2021
<b>1</b>		15 in 1 BOTTLE; Type 0: Not a Combination Product	
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M013	04/28/2021	

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