

**TENSION HEADACHE RELIEF- acetaminophen, caffeine tablet**  
**Pioneer Life Sciences, LLC**

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**Tension Headache Relief (Acetaminophen 500mg and caffeine 65mg)**

**Active Ingredients (in each caplet)**

Acetaminophen 500mg  
Caffeine 65 mg

**Purpose**

Acetaminophen  
500mg.....Pain reliever  
Caffeine 65mg.....  
Pain reliever aid

**Uses:**

temporarily relieves minor aches and pains due to:

- headache
- muscular aches

**Warnings:**

**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.

**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

**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 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 Doctor:**

### **Ask a doctor before use if**

- you have liver disease

## **ASK DOCTOR/PHARMACIST:**

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

- taking the blood thinning drug warfarin

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

- any new symptoms occur
- 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. These could be signs of a serious condition.

## **PREGNANCY**

**If pregnant or breast-feeding,** ask a health professional before use.

## **KEEP OUT OF REACH OF CHILDREN**

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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**

- 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.

## INACTIVE INGREDIENTS

Colloidal Silicon Dioxide, Croscarmellose Sodium, D & C Red # 27, F D & C yellow # 6, F D & C Blue # 2, Microcrystalline Cellulose, Magnesium Stearate, Polyethylene Glycol, Polyvinyl Pyrrolidone, Pregelatinized Starch, Polyvinyl Alcohol, Stearic Acid Powder, Titanium Dioxide, Talc.

## QUESTIONS OR COMMENTS?

Call 1-732-698-5070 Monday through Friday 9AM to 5PM EST.

## PRINCIPAL DISPLAY PANEL

**TAMPER EVIDENT** Do not use if safety seal under cap is broken or missing.

<b>Drug Facts</b>	<p><b>Active Ingredients (in each caplet)</b></p> <ul style="list-style-type: none"> <li>Acetaminophen 500mg</li> <li>Caffeine 65mg</li> </ul> <p><b>USES:</b> Temporarily relieves minor aches and pain due to:                     <ul style="list-style-type: none"> <li>■ headaches</li> <li>■ muscular aches</li> </ul> </p> <p><b>WARNINGS: ALLERGY ALERT:</b> Acetaminophen may cause severe skin reactions. Symptoms may include:                     <ul style="list-style-type: none"> <li>■ skin redness</li> <li>■ blisters</li> <li>■ rash.</li> </ul>                     If a skin reaction occurs, stop use and seek medical help right away.                     <p><b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take                     <ul style="list-style-type: none"> <li>■ no more than 6 caplets in 24 hours, which is the maximum daily amount</li> <li>■ with other drugs containing acetaminophen</li> <li>■ 3 or more alcoholic drinks everyday while using this product.</li> </ul> </p> <p><b>Caffeine warning:</b> 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 heartbeat.</p> <p><b>DO NOT USE:</b> <ul style="list-style-type: none"> <li>■ if you ever had an allergic reaction to acetaminophen</li> <li>■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> </ul> </p> <p><b>Ask a doctor before use if:</b> <ul style="list-style-type: none"> <li>■ you have a liver disease.</li> </ul> </p> <p><b>Ask a doctor or pharmacist before use if you are:</b> <ul style="list-style-type: none"> <li>■ taking the blood thinning drug warfarin.</li> </ul> </p> <p><b>Stop use and ask doctor if:</b> <ul style="list-style-type: none"> <li>■ any new symptoms occur</li> <li>■ painful area is red or swollen</li> <li>■ pain gets worse or lasts for more than 10 days</li> <li>■ fever gets worse or lasts for more than 3 days.</li> </ul>                     These could be signs of a serious condition.                 </p> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use.</p> <p><b>KEEP OUT OF REACH OF CHILDREN.</b> In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults, as well as for children even if you do not notice any signs or symptoms.</p> <p><b>DIRECTIONS:</b> <ul style="list-style-type: none"> <li>■ Do not use more than directed</li> <li>■ adults and children 12 years and over: take 2 caplets every 6 hours, not more than 6 caplets in 24 hours</li> <li>■ children under 12 years: ask a doctor</li> </ul> </p> <p><b>OTHER INFORMATION:</b> <ul style="list-style-type: none"> <li>■ Store at 20°-25°C (68°-77°F)</li> <li>■ close cap tightly after use</li> <li>■ read all product information before using.</li> </ul> </p> <p><b>INACTIVE INGREDIENTS:</b> Colloidal Silicon Dioxide, Croscarmellose Sodium, D &amp; C Red # 27, F D &amp; C Yellow # 6, F D &amp; C Blue # 2, Microcrystalline Cellulose, Magnesium Stearate, Polyethylene Glycol, Polyvinyl Pyrrolidone, Pregelatinized Starch, Polyvinyl Alcohol, Stearic Acid Powder, Titanium Dioxide, Talc.</p> <p><b>QUESTIONS OR COMMENTS?</b> Call 1-732-698-5070 Monday through Friday 9AM to 5PM EST.</p> </p>
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## TENSION HEADACHE RELIEF

acetaminophen, caffeine tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72090-004
<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>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)
<b>TALC</b> (UNII: 7SEV7J4R1U)
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (Capsule shape Tablet)	<b>Size</b>	28mm
<b>Flavor</b>		<b>Imprint Code</b>	None
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72090-004-02	200 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	08/03/2020	

**Labeler** - Pioneer Life Sciences, LLC (014092742)