

# TENSION HEADACHE RELIEF- tension headache relief capsule

## Allegiant Health

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### Drug Facts

#### Active ingredient (in each caplet)

Acetaminophen 500 mg  
Caffeine 65mg

#### Purpose

Pain reliever  
Pain reliever aid

#### Uses

temporary relief of 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 8 tablets in 24 hours, which is the maximum daily amount

■ take with other drugs containing acetaminophen ■ have 3 or more alcoholic drinks every day while using this product

**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.**

**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

■ with any other drug containing acetaminophen (prescription or nonprescription). Ask a doctor or pharmacist before using with other drugs if you are not sure.

Ask doctor before use if you have  
liver disease

**Stop Use and ask a doctor if**

■ any new symptoms occur   ■ symptoms do not get better or worsen   ■ 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

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

In case of accidental overdose, get medical help or contact a PoisonControlCenter immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms

**Directions**

**Do not exceed recommended dosage.**

**Adults and children 12 years and over:** take 2 tablets every 6 hours. Do not take more than 8 tablets in 24 hours

**Children under 12 years:** ask a doctor

**Inactive Ingredients**

corn starch, croscarmellose sodium, crospovidone, D&C red #27 aluminum lake, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, silicon dioxide, stearic acid, titanium dioxide

**Package/Label Principal Display Panel**



Pain Reliever/Pain Reliever Aid

Caplets

## TENSION HEADACHE RELIEF

tension headache relief capsule

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69168-029
<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>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-029-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	11/26/2014	
2	NDC:69168-029-98	200 in 1 BOTTLE; Type 0: Not a Combination Product	11/26/2014	
3	NDC:69168-029-26	20 in 1 BOTTLE; Type 0: Not a Combination Product	01/20/2020	

4	NDC:69168-029-37	1 in 1 CARTON	12/15/2021	
4		16 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:69168-029-50	50 in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	11/26/2014	

**Labeler** - Allegiant Health (079501930)

Revised: 11/2017

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