# TENSION HEADACHE RELIEF- acetaminophen 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™ TENSION HEADACHE RELIEF

#### **Drug Facts**

Active ingredients (in each caplet)	Purposes
Acetaminophen 500 mg	Pain reliever
Caffeine 65 mg	Pain reliever aid

#### Uses

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

## **Warnings**

**Liver Warning:** This product contains acataminophen. Severe liver damage may occure if you take.

- more than 6 caplets in 24 hours, whihe 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

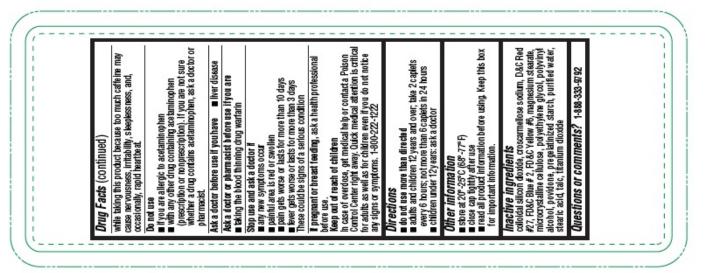
Compare to the active ingredients in EXCEDRIN® TENSION HEADACHE\*

Tension Headache Relief

Acetaminophen & Caffeine Pain Reliever/ Pain reliever aid







#### TENSION HEADACHE RELIEF

acetaminophen and caffeine tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0190	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	500 mg		
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg		

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
PO VIDO NE K30 (UNII: U725QWY32X)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Characteristics				
Color	red	Score	no score	
Shape	OVAL (CAPSULE SHAPED TABLET)	Size	18 mm	
Flavor		Imprint Code	S431	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:68210-0190- 2	1 in 1 CARTON	04/10/2018		
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
2	NDC:68210-0190-	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2018		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
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(68210-0190)	