TENSION HEADACHE RELIEF- acetaminophen and caffeine tablet
SPIRIT PHARMACEUTICALS LLC

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, whihc 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 & Caffeine

Pain Reliever/ Pain reliever aid

Actual Size

TENSION HEADACHE RELIEF

acetaminophen and caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68210-4108
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

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

Contains

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-4108-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2020	
2	NDC:68210-4108-2	200 in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2020	
3	NDC:68210-4108-5	150 in 1 BOTTLE; Type 0: Not a Combination Product	10/22/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	08/05/2020	

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

Revised: 12/2023 SPIRIT PHARMACEUTICALS LLC