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, 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

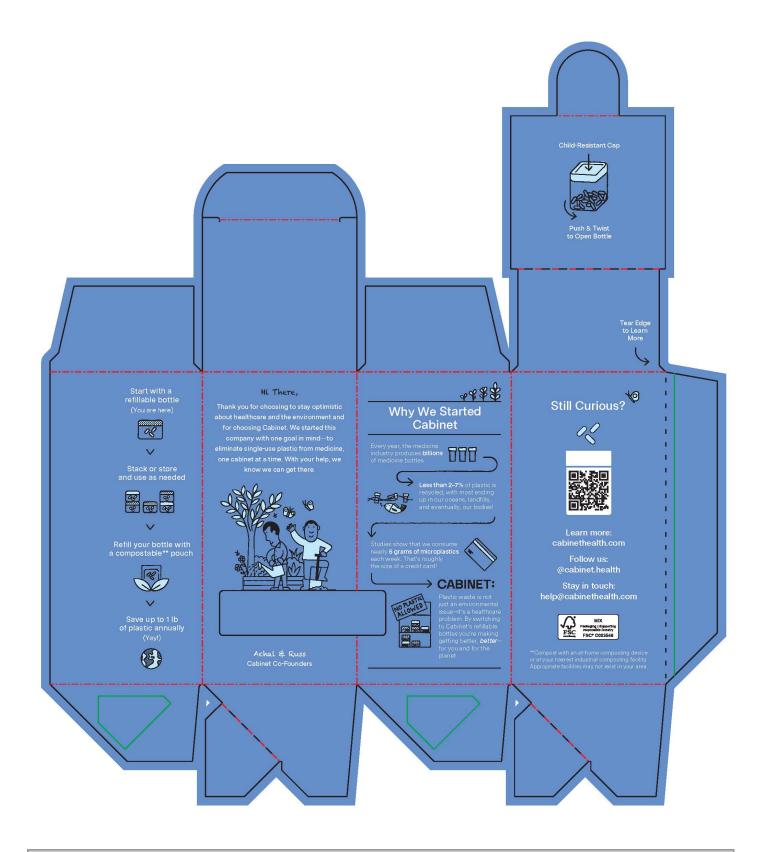
colloidal silicon dioxide, croscarmellose sodium, D&C Red#27, FD&C Blue#2, FD&C Yellow#6, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, purified water, stearic acid, talc, titanium dioxide

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL





TENSION HEADACHE RELIEF

acetaminophen and caffeine tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-4239
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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: 3WJQ0SDW1A)			
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	CAPSULE (CAPSULE SHAPED TABLET)	Size	18mm
Flavor		Imprint Code	S431
Contains			

Packaging				
# Iten	n Code	Package Description	Marketing Start Date	Marketing End Date
NDC:68	3210-4239-	1 in 1 CARTON	12/29/2022	
1		100 in 1 JAR; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	12/29/2022	

Labeler - Spirit Pharmaceuticals LLC (179621011)

Revised: 12/2023 Spirit Pharmaceuticals LLC