TENSION HEADACHE RELIEF- acetaminophen and caffeine tablet, film coated Spirit Pharmaceuticals LLC

Tension Headache Relief

Drug Facts

Active Ingredient (in each tablet)

Acetaminophen 500 mg Caffeine 65 mg

Purpose

Pain reliever Pain reliever aid

Uses

Temporarily relieves 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 6 tablets 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

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, 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 non prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if you have

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 for 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 tablets every 6 hours; not more than 6 tablets 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 No. 27, FD&C Blue No. 2, FD&C Yellow No. 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

Distributed by:

Cabinet Health P.B.C.

Pouch

PACKAGE NOT CHILD-RESISTANT CABINET:

Tension Headache Relief

Compare to the active ingredients in: Excedrin® Tension Headache*

Active ingredients: ACETAMINOPHEN 500 MG CAFFEINE 65 MG

Relieves: Headache Fever Muscle Aches and Pains Menstrual Cramps

COMPOSTABLE REFILL POUCH

Includes:

30 x Caplets

1 x Magnetic Label

1 x Drug Facts Booklet



CABINET: The Sustainable Healthcare Co.™

acetaminophen and caffeine tablet, film coated

Product Information

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
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
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 (UNII: FZ 989GH94E)	
STARCH, 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	Size	18mm	
Flavor		Imprint Code	S431	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:68210- 4184-3	30 in 1 POUCH; Type 0: Not a Combination Product	11/22/2021		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	11/22/2021	

Labeler - Spirit Pharmaceuticals LLC (179621011)

Revised: 12/2024 Spirit Pharmaceuticals LLC