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

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**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**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-4184

**Route of Administration** ORAL

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	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)		
<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)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)		
POVIDONE (UNII: FZ989GH94E)		
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			

Ш	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	<b>1</b> 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: 12/2023 Spirit Pharmaceuticals LLC