

EXTRA STRENGTH HEADACHE RELIEF- acetaminophen, aspirin, and caffeine tablet, coated
Spirit Pharmaceuticals LLC

Extra Strength Headache Relief

Drug Facts

Active Ingredient (in each tablet)

Acetaminophen

Aspirin

Caffeine

Purpose

Pain reliever

Pain reliever

Pain reliever aid

Uses

• temporarily relieves minor aches and pains due to: • headache • a cold • arthritis • muscular aches • sinusitis • toothache • premenstrual & menstrual cramps

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.
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. Aspirin may cause a severe allergic reaction which may include: • hives • facial swelling • asthma (wheezing) • shock

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

• more than 8 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
Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause stomach bleeding. The chance is higher if you • are age 60 or older • have had stomach ulcers or bleeding problems • take a

blood thinning (anticoagulant) or steroid drug • take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) • have 3 or more alcoholic drinks every day while using this product • take more or for a longer time than directed

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 have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer • 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 • stomach bleeding warning applies to you • you have a history of stomach problems, such as heartburn • you have high blood pressure, heart disease, liver cirrhosis or kidney disease • you are taking a diuretic • you have asthma

Ask a doctor or pharmacist before use if you are taking

- any other drug containing an NSAID (prescription or non-prescription) • a prescription drug for diabetes, gout or arthritis • any other drug, or are under a doctor's care for any serious condition • a blood thinning (anticoagulant) or steroid drug

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away. • you experience any of the following signs of stomach bleeding • feel faint • vomit blood • have bloody or black stools • have stomach pain that does not get better • ringing in the ears or loss of hearing occurs • 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 • any new symptoms appear. These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

Overdose warning:

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

• **do not use more than directed (see Overdose warning)** • drink a full glass of water with each dose • adults and children 12 years and over: take 2 tablets every 6 hours; not more than 8 tablets in 24 hours • children under 12 years: ask a doctor

Other Information

• store at controlled room temperature 20°-25° C (68°-77° F) • read all product information before using

Inactive ingredients

Colloidal silicon dioxide, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, stearic acid, talc

Questions or comments?

1-888-333-9792

Distributed by:

Cabinet Health P.B.C.

Pouch

PACKAGE NOT CHILD-RESISTANT



CABINET:

Extra Strength Headache Relief

Compare to the active ingredients in:
Excedrin® Extra Strength*

Active ingredients:

ACETAMINOPHEN 250 MG

ASPIRIN 250 MG (NSAID)**

CAFFEINE 65 MG

**NONSTEROIDAL ANTI-INFLAMMATORY DRUG

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

Certified



CABINET: The Sustainable Healthcare Co.™

EXTRA STRENGTH HEADACHE RELIEF

acetaminophen, aspirin, and caffeine tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-4183
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, POTATO (UNII: 8I089SAH3T)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	S53
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-4183-3	30 in 1 POUCH; Type 0: Not a Combination Product	11/19/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	11/19/2021	

Labeler - Spirit Pharmaceuticals LLC (179621011)

Revised: 12/2023

Spirit Pharmaceuticals LLC