

NUVICARE HEADACHE RELIEF- acetaminophen, aspirin, caffeine tablet
NUVICARE LLC

Headache Relief

Active Ingredients (in each caplet)

Acetaminophen 250 mg

Aspirin 250 mg

Caffeine 65 mg

Purpose

Acetaminophen 250 mg.....Pain reliever

Aspirin 250 mg (NSAID*).....Pain reliever

Caffeine 65 mgPain reliever aid

(*nonsteroidal anti-inflammatory drug)

Uses:

temporarily relieves minor aches and pains due to:

- headache
- a cold
- arthritis
- muscular aches
- 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.

Allergy alert: 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 gels 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 an NSAID, which may cause severe 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 heart beat.

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 Doctor:

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 DOCTOR/PHARMACIST:

Ask a doctor or pharmacist before use if you are taking

- a prescription drug for diabetes, gout, or arthritis
- any other drug, or are under a doctor's care for any serious condition

Stop use and ask 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 for more than 10 days

■ fever gets worse or lasts more than 3 days

■ any new symptoms occur. These could be signs of a serious condition.

PREGNANCY

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin at 20 weeks or later in 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. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. 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**

■ drink a full glass of water with each dose

■ adults and children 12 years of age and over: take 2 caplets every 6 hours; not more than 8 caplets in 24 hours

■ children under 12 years: ask a doctor

OTHER INFORMATION

■ Store between 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, Hypromellose, Microcrystalline Cellulose, Polyethylene Glycol, Pregelatinized Starch, Polyvinyl Pyrrolidone, Stearic Acid Powder, Talc.

QUESTIONS OR COMMENTS?

Call 1 (718) 337-8733 or visit: support@nuvicare.com



Compare to
Excedrine®
Extra Strength
active ingredients.

EXTRA STRENGTH

Headache Relief

Acetaminophen 250 mg
Aspirin 250 mg (NSAID)
Caffeine 65 mg

100
caplets

not actual size

Drug Facts

Active Ingredients (in each caplet):

- Acetaminophen 250 mg Pain reliever
- Aspirin 250 mg (NSAID)* Pain reliever
- Caffeine 65 mg Pain reliever aid (nonsteroidal anti-inflammatory drug)

USES: temporarily relieves minor aches and pains due to:

- headache ■ a cold ■ arthritis ■ muscular aches ■ 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 redness ■ blisters ■ rash. If a skin reaction occurs, stop use and seek medical help right away.

ALLERGY ALERT: 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 caplets 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 an NSAID, which may cause severe 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, ...)

(continued under label)

†This product is not manufactured or distributed by GSK/Consumer Health, owner of the registered trademark **EXCEDRIN® Extra Strength Tablets**.

Distributed by: Nuvicare LLC, Brooklyn, NY
www.nuvicare.com



Lot No.
Exp. Dt

PEEL HERE

Drug Facts (continued)

naproxen, or others) ■ have 3 or more alcoholic drinks 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 heart beat.

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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 ■ a prescription drug for diabetes, gout, or arthritis ■ any other drug, or are under a doctor's care for any serious condition.

Stop use and ask 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 for more than 10 days ■ fever gets worse or lasts more than 3 days ■ any new symptoms occur. These could be signs of a serious condition.

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INACTIVE INGREDIENTS: Colloidal Silicon Dioxide, Hypromellose, Microcrystalline Cellulose, Polyethylene Glycol, Pregelatinized Starch, Polyvinyl Pyrrolidone, Stearic Acid Powder, Talc.

QUESTIONS OR COMMENTS? Call 1 (718) 337-8733 or visit: support@nuvicare.com

Glue Area

NUVICARE HEADACHE RELIEF

acetaminophen, aspirin, caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84324-007
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	27mm
Flavor		Imprint Code	S53
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84324-007-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/17/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/17/2024	

Labeler - NUVICARE LLC (119257565)

Registrant - NUVICARE LLC (119257565)

Revised: 7/2024

NUVICARE LLC