

HEADACHE RELIEF EXTRA STRENGTH- acetaminophen, aspirin, caffeine tablet

Rite Aid Corporation

Drug Facts

Active ingredients (in each tablet)

Acetaminophen 250 mg

Aspirin 250 mg (NSAID)*

Caffeine 65 mg

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever

Pain reliever

Pain reliever aid

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - a cold
 - arthritis
 - muscular aches
 - toothache
 - premenstrual and 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: Aspirin may cause a severe allergic reaction, which may include:

- hives
- facial swelling
- shock
- asthma (wheezing)

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

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

- more than 4,000 mg of acetaminophen in 24 hours
- 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 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 history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you have asthma
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for diabetes, gout, or arthritis
- taking 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.
 - any new symptoms appear
- 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
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- painful area is red or swollen

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.

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**
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 gels every 6 hours; do not take more than 8 caplets in 24 hours
- children under 12 years: do not use unless directed by a doctor

Other information

- store between 20°-25°C (68°-77°F)

Inactive ingredients

black printing ink, corn starch, D&C yellow #10 aluminum lake, edetate disodium, FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, gelatin, glycerin, hydroxypropyl cellulose, hydroxypropyl cellulose-low substituted, hypromellose, iron oxide black, maltitol, povidone, purified water, stearic acid, talc, titanium dioxide

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

†Compare to the active ingredients in Excedrin® Extra Strength

EXTRA STRENGTH

HEADACHE RELIEF

ACETAMINOPHEN 250 mg • ASPIRIN (NSAID)* 250 mg • CAFFEINE 65 mg

PAIN RELIEVER

PAIN RELIEVER AID

GELTABS

†This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Excedrin® Extra Strength.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY: RITE AID,

30 HUNTER LANE,

CAMP HILL, PA 17011

www.riteaid.com

Package Label

Exp. Date:
Lot No.:

PLD-05148 F0007084



DISTRIBUTED BY:
RITE AID, 30 HUNTER LANE,
CRAMP HILL, PA 17011
www.riteaid.com

**SATISFACTION
GUARANTEE**
If you're not satisfied, we'll
happily refund your money!

NDC 11822-7888-5

[†]Compare to the active ingredients in
Excedrin[®] Extra Strength

EXTRA STRENGTH HEADACHE RELIEF

ACETAMINOPHEN 250 mg • ASPIRIN (NSAID) 250 mg • CAFFEINE 65 mg

PAIN RELIEVER
PAIN RELIEVER AID

ACTUAL SIZE

80
GELTABS



Drug Facts (continued)

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Directions

- do not use more than directed
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Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- any new symptoms appear
- 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
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Aspirin 250 mg (NSAID)*.....Pain reliever
Caffeine 65 mg.....Pain reliever aid
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Take more or for a longer time than directed

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RITE AID Extra Strength Headache Relief

HEADACHE RELIEF EXTRA STRENGTH

acetaminophen, aspirin, caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-7888
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
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
MALTITOL (UNII: D65DG142WK)	
WATER (UNII: 059QF0KO0R)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	13mm
Flavor		Imprint Code	P
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-7888-5	1 in 1 BOX	02/28/2020	
1		80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:11822-7888-4	1 in 1 BOX	02/28/2020	
2		20 in 1 BOTTLE, PLASTIC; 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	02/28/2020	

Labeler - Rite Aid Corporation (014578892)

Revised: 5/2024

Rite Aid Corporation