

EXTRA STRENGTH HEADACHE RELIEF- acetaminophen, aspirin, and caffeine tablet, coated
Dollar General

Extra Strength Headache Relief

Drug Facts

Active ingredients (in each caplet)

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 & menstrual cramps

Warnings

Reye's syndrome: Children and teenagers who 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 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 no prescription 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 occasional 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 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 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 3 days

any new symptoms occur

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: Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away

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 caplets every 6 hours; not more than 8 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- **each tablet contains:** sodium 5.1mg (low sodium)
- store at room temperature between 20-25C (68 to 77F)
- avoid excessive heat, cold and humidity
- close cap tightly after use
- read all products information before using.

Inactive ingredients

croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polacrillin potassium, polyethylene glycol, polyvinyl alcohol, povidone, purified talc, sodium lauryl sulphate, sodium starch glycolate, starch, titanium dioxide

Questions or comments?

1-888-577-8033 Monday-Friday 8am-4pm

DG™ health

Compare to the active ingredients of Excedrin® Extra Strength††

READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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

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

DISTRIBUTED BY OLD EAST MAIN CO.
100 MISSION RIDGE
GOODLETTSVILLE, TN 37072

MADE IN INDIA

100%
Satisfaction Guaranteed!
(888) 309-9030

Packaging



NDC - 55910-440-01

DG health

Compare to the active ingredients of Excedrin® Extra Strength!

Extra Strength Headache Relief

Acetaminophen, Aspirin (NSAID) and Caffeine
Pain Reliever / Pain Reliever Aid

100 Caplets
Actual Caplet Size

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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 caplets in 24 hours, which is the maximum daily amount
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 ■ 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
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Drug Facts (continued)

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 ■ 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
 ■ 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 a doctor if
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 ■ 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 3 days
 any new symptoms occur
 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.

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Drug Facts (continued)

Other information
 ■ each caplet contains sodium 5.1mg (low sodium)
 ■ store at room temperature between 20-25°C (68 to 77°F)
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 ■ close cap tightly after use
 ■ read all product information before using

Inactive ingredients mesorizalene sodium, mesopropyl stearate, microcrystalline cellulose, croscarmellose sodium, polyethylene glycol, polyvinyl alcohol, pyridone, purified talc, sodium lauryl sulfate, sodium starch glycolate, starch, titanium dioxide

Questions or comments?
 1-888-571-8833 Monday-Friday 8am-4pm

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Stop use and ask a doctor if
 ■ an allergic reaction occurs. Seek medical help right away.
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 ■ have stomach pain that does not get better
 ■ ringing in the ears or loss of hearing occurs
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damage may occur if you take

- more than 8 caplets in 24 hours, which is the maximum daily amount
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- 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

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EXTRA STRENGTH HEADACHE RELIEF

acetaminophen, aspirin, and caffeine tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-440
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) (ACETYLSALICYLIC ACID - UNII:R16CO5Y76E)	ASPIRIN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6130)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
POLACRILIN POTASSIUM (UNII: 0BZ5A00FQU)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)
TALC (UNII: 7SEV7J4R1U)
SODIUM LAURYL SULFATE (UNII: 368GB5141J)
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)
STARCH, CORN (UNII: O8232NY3SJ)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	S142
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-440-01	1 in 1 CARTON	05/01/2021	
1		100 in 1 BOTTLE; 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	05/01/2021	

Labeler - Dollar General (068331990)