

**KROGER EXTRA STRENGTH HEADACHE RELIEF GELTAB- acetaminophen,
aspirin, caffeine tablet, film coated
The Kroger Co.**

Extra Strength Headache Relief GELTAB

Drug Facts

Active ingredients (in each geltab)

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: 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 geltabs 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 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 10 days
- fever 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.

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

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

Other information

- each geltab contains: **sodium 5mg** (low sodium)
- store at room temperature between 20°-25°C (68°-77°F)

Inactive ingredients

corn starch, D&C yellow #10 aluminum lake, edible black ink, ethyl cellulose, FD&C blue#1, FD&C blue#1 aluminum lake, FD&C red #40 aluminum lake, gelatin, glycerin, hypromellose, isopropyl alcohol, lactose monohydrate, light mineral oil, microcrystalline cellulose, povidone, pregelatinized potato starch, purified water, sorbitol sorbitan solution, stearic acid, talc, titanium dioxide, triacetin

Questions or comments?

call **800-632-6900**

COMPARE TO THE ACTIVE INGREDIENTS IN EXCEDRIN® EXTRA STRENGTH

***See bottom panel**

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 THE KROGER CO.

CINCINNATI, OHIO 45202

Product of United Arab Emirates

READ AND KEEP OUTER CARTON FOR COMPLETE PRODUCT WARNINGS AND INFORMATION

Packaging



Headache Relief

Acetaminophen 250 mg - Pain Reliever
Aspirin (NSAID) 250 mg - Pain Reliever
Caffeine 65 mg - Pain Reliever Aid



80 GELTABS

COMPARE TO THE ACTIVE INGREDIENTS IN
EXCEDRIN® EXTRA STRENGTH *See bottom panel

NDC 59450-600-80

Extra Strength Headache Relief

Acetaminophen 250 mg - Pain Reliever
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NO VARNISH
REV 00-012024
C75945060080

Questions or comments: Call 800-632-6900

Inactive ingredients
corn starch, D&C yellow #10 aluminum lake, edible black ink, ethyl aluminum lake, gelatin, glycerin, hypromellose, isopropyl alcohol, lactose monohydrate, light mineral oil, microcrystalline cellulose, polydextrose, pregelatinized potato starch, purified water, sorbitol solution, stearic acid, talc, titanium dioxide, triacetin

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Allegation alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ● skin reddening ● blisters ● rash

Allegation alert: Aspirin may cause a severe allergic reaction which may include:
● hives ● facial swelling ● asthma (wheezing) ● shock

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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 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 10 days ● fever gets worse or lasts for more than 3 days ● any new symptoms occur

DRUG FACTS LABEL

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Caffeine 65 mg.....Pain reliever aid
*nonsteroidal anti-inflammatory drug

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Drug Facts (Continued)

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Questions or comments: Call 800-632-6900

Common bleeding warning. This product contains aspirin, 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
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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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KROGER EXTRA STRENGTH HEADACHE RELIEF GELTAB

acetaminophen, aspirin, caffeine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59450-600
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)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, POTATO (UNII: 8I089SAH3T)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	green, white	Score	no score
Shape	ROUND	Size	13mm
Flavor		Imprint Code	S77
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59450-600-80	1 in 1 CARTON	02/01/2024	
1		80 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	02/01/2024	

Labeler - The Kroger Co. (006999528)

Revised: 1/2024

The Kroger Co.