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

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## 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

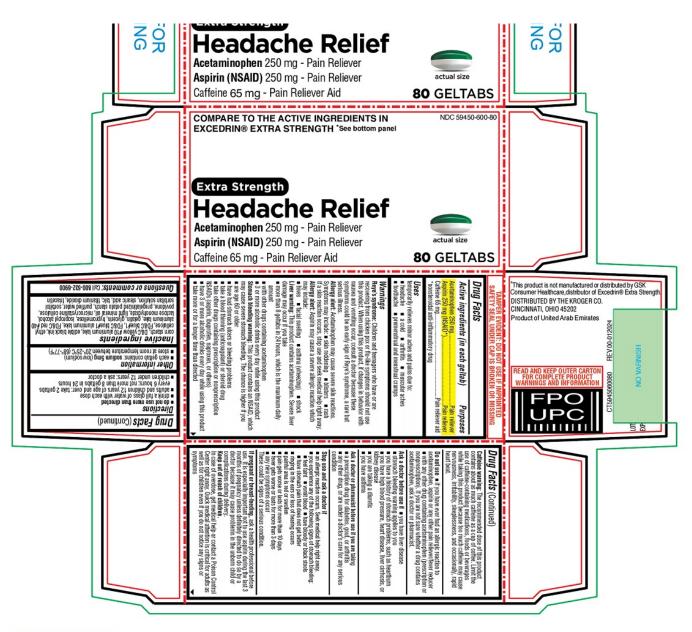
\*This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Excedrin® Extra Strength

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**





#### **DRUG FACTS LABEL**

damage may occur if you take

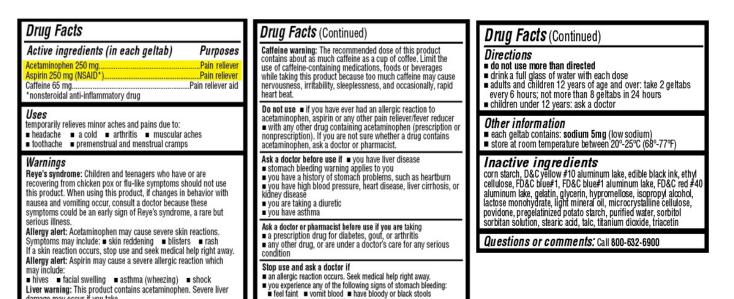
■ with other drugs containing acetaminophen

amount

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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	<b>Basis of Strength</b>	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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: 81089SAH3T)		
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				

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