

## **HEADACHE RELIEF EXTRA STRENGTH- acetaminophen, aspirin, caffeine tablet The Kroger Co.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **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
- shock
- asthma (wheezing)

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

- adults 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 a 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.

- 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 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 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 **1-800-632-6900**

### **Principal Display Panel**

COMPARE TO the active ingredients in EXCEDRIN® EXTRA STRENGTH †See bottom panel

### **Extra Strength**

Headache Relief

Acetaminophen 250 mg - Pain Reliever

Aspirin (NSAID) 250 mg - Pain Reliever

Caffeine 65 mg -Pain Reliever Aid

GELTABS

†Excedrin® is a registered trademark of GSK Consumer Healthcare SARL, Prangins, Switzerland 1197. GSK Consumer Healthcare SARL is not affiliated with The Kroger Co. or this product.

**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 THE KROGER CO.

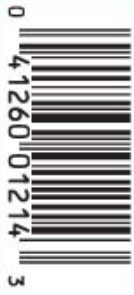
CINCINNATI, OHIO 45202

**Package Label**

Exp. Date:

Lot No.:

P1D-8S14C F0008564



### Drug Facts

#### Active ingredients (in each geltab)

Acetaminophen 250 mg ..... Pain reliever  
Aspirin 250 mg (NSAID)\* ..... Pain reliever  
Caffeine 65 mg ..... Pain reliever aid

\*nonsteroidal anti-inflammatory drug

#### Uses

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  - headache
  - a cold
  - arthritis
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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, shock.

**Asthma (wheezing)**

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### Drug Facts (continued)

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.

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- taking 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
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#### Other information

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#### Inactive ingredients

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#### Questions or comments? Call 1-800-632-6800

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**DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202**

**FOR MORE PRODUCT INFORMATION, SCAN UPC USING YOUR KROGER APP OR CALL 800-632-6800**

**LOVE IT OR YOUR MONEY BACK. WWW.KROGER.COM**



COMPARE TO the active ingredients in EXCEDRIN® EXTRA STRENGTH \*See bottom panel

NDC 30142-586-80



Extra Strength

# Headache Relief

Acetaminophen 250 mg - Pain Reliever

Aspirin (NSAID) 250 mg - Pain Reliever

Caffeine 65 mg - Pain Reliever Aid



actual size



## 80 GELTABS

# KROGER Extra Strength Headache Relief

## HEADACHE RELIEF EXTRA STRENGTH

acetaminophen, aspirin, caffeine tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:30142-586
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYDROXYPROPYL CELLULOSE, UNSPECIFIED</b> (UNII: 9XZ8H6N6OH)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>FERROSOFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>MALTITOL</b> (UNII: D65DG142WK)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED</b> (UNII: 2165RE0K14)	

### Product Characteristics

<b>Color</b>	green, white	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	P
<b>Contains</b>			

### Packaging

		<b>Marketing Start</b>	<b>Marketing End</b>
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-586-20	1 in 1 BOX	03/31/2019	
1		20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:30142-586-80	1 in 1 BOX	03/31/2019	
2		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 not final	part343	03/31/2019	

**Labeler** - The Kroger Co. (006999528)

Revised: 6/2023

The Kroger Co.