

**EXCEDRIN EXTRA STRENGTH HEADACHE- acetaminophen, aspirin,
caffeine tablet, film coated**
JC World Bell Wholesale Co., Inc

Excedrin Extra Strength Headache

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 250 mg

Aspirin 250 mg (NSAID*)

Caffeine 65 mg

Purposes

Pain reliever

Pain reliever

Pain reliever aid

*nonsteroidal anti-inflammatory drug

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

Other information

- store at 20°-25°C (68-77°F)
- close cap tightly after use
- read all product information before using. Keep this box for important information.

Inactive ingredients

benzoic acid, carnauba wax, FD&C blue no. 1, hypromellose, light mineral oil, low-substituted hydroxypropyl cellulose, microcrystalline cellulose, polysorbate 20, povidone, propylene glycol, simethicone, sorbitan monolaurate, stearic acid, titanium dioxide

Questions or comments?

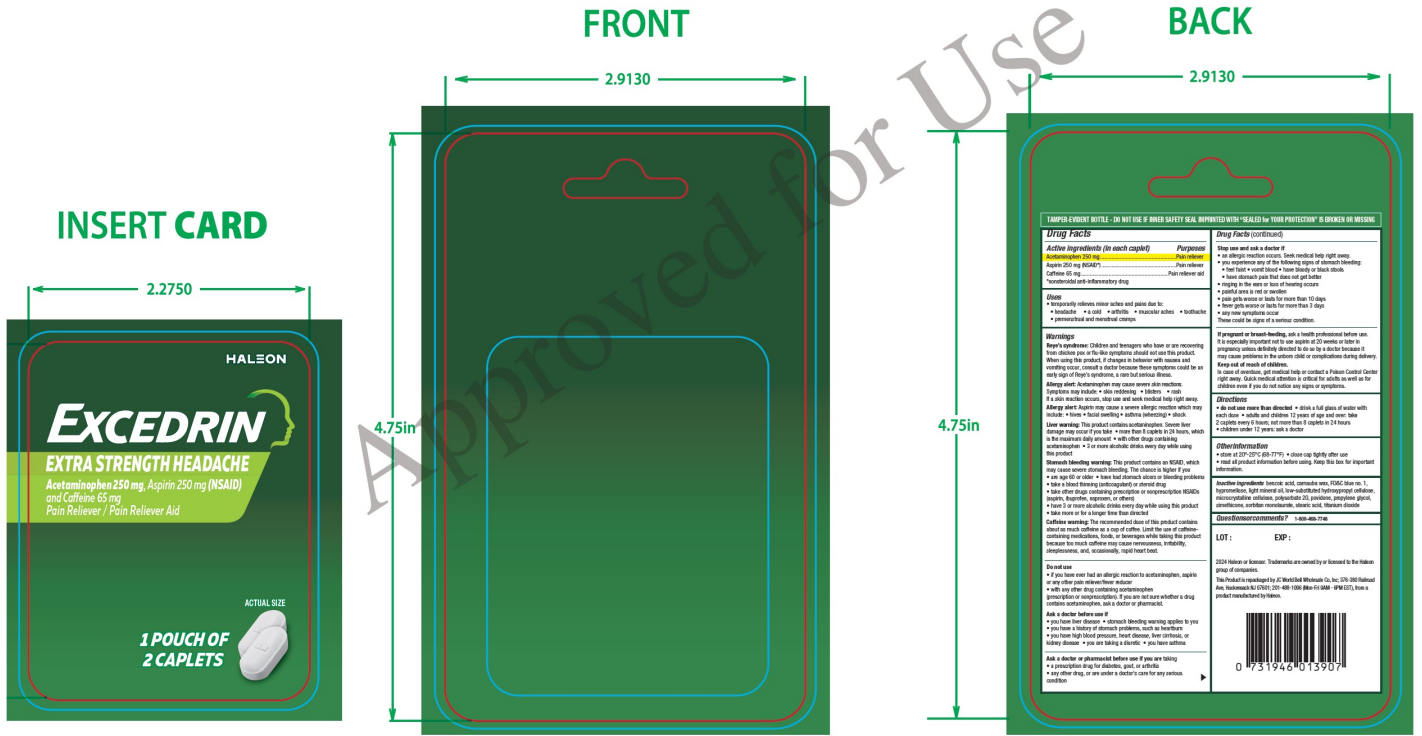
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Package Labeling: 50269-158-01

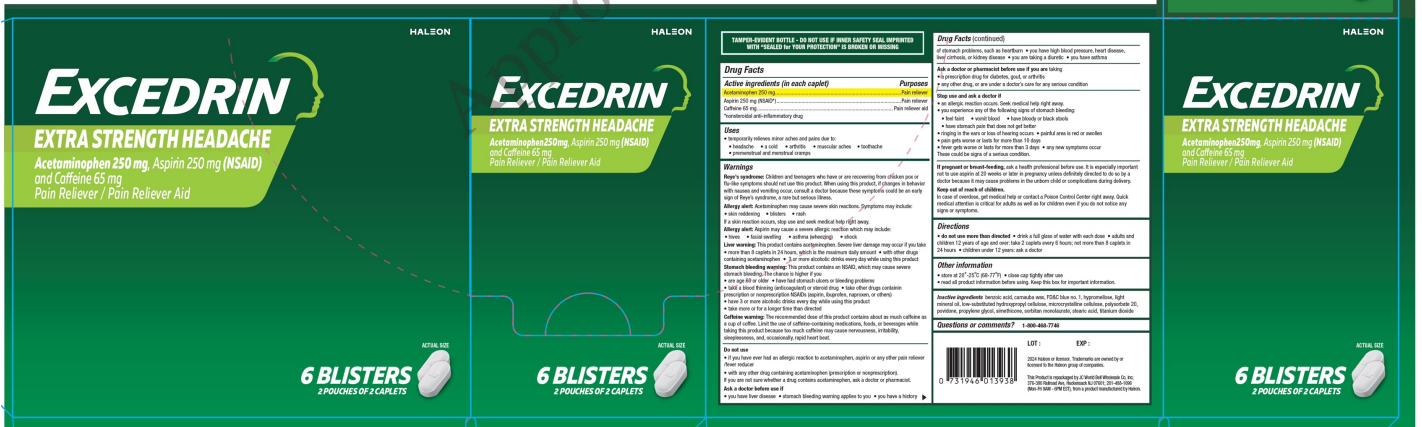


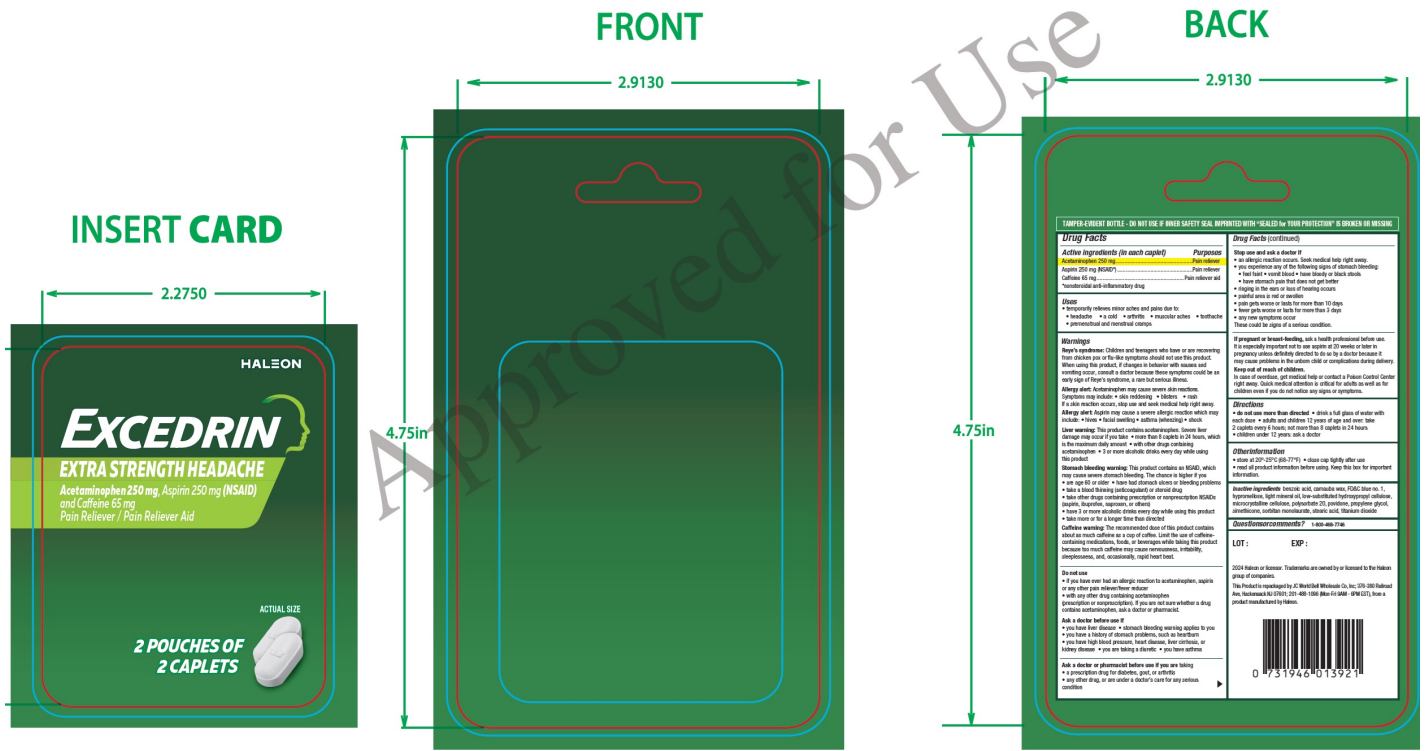
Package Labeling: 50269-158-02





Package Labeling: 50269-158-03





EXCEDRIN EXTRA STRENGTH HEADACHE

acetaminophen, aspirin, caffeine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50269-158(NDC:0067-2002)
Route of Administration	TOPICAL		

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
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 2165RE0K14)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

SORBITAN MONOLAURATE (UNII: 6W9PS8B71J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	white	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	E
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50269-158-01	25 in 1 BOX	01/01/2024	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:50269-158-02	6 in 1 BOX	01/01/2024	
2		1 in 1 BLISTER PACK		
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:50269-158-03	6 in 1 BOX	01/01/2024	
3		2 in 1 BLISTER PACK		
3		2 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020802	01/01/2024	

Labeler - JC World Bell Wholesale Co., Inc (805257581)

Establishment			
Name	Address	ID/FEI	Business Operations
Haleon US Inc.		129836151	manufacture(50269-158)

Establishment			
Name	Address	ID/FEI	Business Operations
JC World Bell Wholesale Co., Inc.		805257581	repack(50269-158)