

EXCEDRIN MIGRAINE RELIEF- acetaminophen, aspirin (nsaid), caffeine tablet, film coated

Haleon US Holdings LLC

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 250mg

Aspirin 250 mg (NSAID*)

Caffeine 65 mg

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever

Pain reliever

Pain reliever aid

Use

- treats migraine

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 2 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

Medication overuse headache warning: Headaches may worsen if this product is used for 10 or more days per month.

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 doctor before use if

• you have never had migraines diagnosed by a health professional • you have a headache that is different from your usual migraines • you have the worst headache of your life • you have fever and stiff neck • you have headaches beginning after or caused by head injury, exertion, coughing or bending • you experienced your first headache after the age of 50 • you have daily headaches • you have a migraine so severe as to require bed rest • 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 • you have problems or serious side effects from taking pain relievers or fever reducers • you have vomiting with your migraine headache

Ask a doctor or pharmacist before use if you are

• taking a prescription drug for: • diabetes • gout • arthritis • under a doctor's care for any serious condition • taking any other drug • taking any other product that contains aspirin, acetaminophen, or any other pain reliever/fever reducer

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 • your migraine is not relieved or worsens after first dose • new or unexpected symptoms occur • ringing in the ears or loss of hearing occurs

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** • adults: take 2 caplets with a glass of water • if symptoms persist or worsen, ask your doctor • do not take more than • 2 caplets in 24 hours, unless directed by a doctor
- under 18 years of age: ask a doctor

Other information

- store at controlled room temperature 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?

1-800-468-7746

Principal Display Panel

EXCEDRIN

MIGRAINE RELIEF

Acetaminophen 250 mg, Aspirin 250 mg (NSAID)
and Caffeine 65 mg
Pain Reliever / Pain Reliever Aid

ACTUAL SIZE

24

CAPLETS*

****CAPSULE-SHAPED TABLETS***

Distributed by: Haleon, Warren, NJ 07059

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TAMPER-EVIDENT BOTTLE

DO NOT USE IF INNER FOIL SEAL IMPRINTED WITH
"SEALED for YOUR PROTECTION" IS BROKEN OR MISSING

HALEON

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0067-2042
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
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, UNSPECIFIED (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 (Capsule-shaped tablet)	Size	16mm
Flavor		Imprint Code	E
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-2042-01	1 in 1 CARTON	01/01/2024	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0067-2042-02	1 in 1 CARTON	01/01/2024	
2		30 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0067-2042-03	1 in 1 CARTON	01/01/2024	
3		50 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0067-2042-04	1 in 1 CARTON	01/01/2024	
4		100 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0067-2042-05	1 in 1 CARTON	01/01/2024	
5		125 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:0067-2042-06	1 in 1 CARTON	01/01/2024	
6		200 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:0067-2042-07	1 in 1 CARTON	01/01/2024	
7		250 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:0067-2042-08	300 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2024	

Marketing Information

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

Labeler - Haleon US Holdings LLC (079944263)

Revised: 3/2025

Haleon US Holdings LLC