EXCEDRIN MIGRAINE- acetaminophen, aspirin (nsaid) and caffeine tablet, film coated
Haleon US Holdings LLC

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 250 mg
Aspirin 250 mg (NSAID*)
Caffeine 65 mg

* nonsteroidal anti-inflammatory drug

Purpose

Pain reliever
Pain reliever
Pain reliever aid

Uses

- 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 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**
- 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 #1, hydroxypropylcellulose, hypromellose, light mineral oil, microcrystalline cellulose, polysorbate 20, povidone, propylene glycol, simethicone emulsion, sorbitan monolaurate, stearic acid, titanium dioxide

Questions or comments?

1-800-468-7746

Principal Display Panel

NDC 0067-2039-24

See new warnings information

EXCEDRIN®

MIGRAINE

Acetaminophen, Aspirin (NSAID) and Caffeine

Pain Reliever/Pain Reliever Aid

24

*CAPLETS**

**CAPSULE-SHAPED TABLETS*

TAMPER-EVIDENT BOTTLE

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

Distributed by: **GSK Consumer Healthcare,** Warren, NJ 07059

Visit us at www.excedrin.com

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EXCEDRIN MIGRAINE

acetaminophen, aspirin (nsaid) and caffeine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0067-2039
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)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
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 (White)	**Score**	no score
Shape	CAPSULE (Capsule shaped tablet)	**Size**	18mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-2039-02	2 in 1 POUCH; Type 0: Not a Combination Product	02/15/2010	
2	NDC:0067-2039-08	1 in 1 CARTON	02/15/2010	12/31/2014
2		8 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0067-2039-09	1 in 1 CARTON	02/15/2010	07/31/2017
3		10 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0067-2039-24	1 in 1 CARTON	02/15/2010	
4		24 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0067-2039-30	1 in 1 CARTON	02/15/2010	
5		30 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:0067-2039-50	1 in 1 CARTON	02/15/2010	
6		50 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:0067-2039-94	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2010	12/31/2012
8	NDC:0067-2039-91	1 in 1 CARTON	02/15/2010	
8		100 in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:0067-2039-83	1 in 1 CARTON	02/15/2010	
9		125 in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:0067-2039-84	125 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2010	07/31/2014
11	NDC:0067-2039-86	1 in 1 CARTON	02/15/2010	12/31/2014
11		125 in 1 BOTTLE; Type 0: Not a Combination Product		
12	NDC:0067-2039-92	1 in 1 CARTON	02/15/2010	

12		200 in 1 BOTTLE; Type 0: Not a Combination Product		
13	NDC:0067-2039-77	1 in 1 CARTON	02/15/2010	
13		250 in 1 BOTTLE; Type 0: Not a Combination Product		
14	NDC:0067-2039-07	250 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2010	12/31/2012
15	NDC:0067-2039-33	1 in 1 CARTON	02/15/2010	
15		300 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020802	02/15/2010	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 6/2025 Haleon US Holdings LLC