EXCEDRIN MIGRAINE- acetaminophen, aspirin, 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

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 a 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?

1-800-468-7746

Additional Information

TAMPER-EVIDENT BOTTLE

DO NOT USE IF INNER FOIL SEAL INPRINTED WITH “SEALED for YOUR PROTECTION”

IS BROKEN OR MISSING

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

Principal Display Panel

NDC 0067-2040-04

EXCEDRIN

MIGRAINE

Acetaminophen, Aspirin (NSAID) and Caffeine

Pain Reliever/Pain Reliever Aid

50 *CAPLETS*

**CAPSULE-SHAPED TABLETS*

6414070 Front Carton

NDC 0067-2040-04

EXCEDRIN MIGRAINE

acetaminophen, aspirin, and caffeine tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0067-2040
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)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIMETHICONE, UNSPECIFIED (UNII: 92RU3N3Y1O)	
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:0067-2040-02	1 in 1 CARTON	09/30/2020	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0067-2040-03	1 in 1 CARTON	09/30/2020	
2		30 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0067-2040-04	1 in 1 CARTON	09/30/2020	
3		50 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0067-2040-05	1 in 1 CARTON	09/30/2020	
4		100 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0067-2040-06	1 in 1 CARTON	09/30/2020	
5		125 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:0067-2040-07	1 in 1 CARTON	09/30/2020	
6		200 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:0067-2040-08	1 in 1 CARTON	09/30/2020	
7		250 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:0067-2040-09	1 in 1 CARTON	09/30/2020	
8		300 in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:0067-2040-01	2 in 1 POUCH; Type 0: Not a Combination Product	01/31/2021	
10	NDC:0067-2040-11	1 in 1 PACKAGE	03/06/2023	
10		8 in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
NDA	NDA020802	09/30/2020	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 3/2025 Haleon US Holdings LLC