

# **EXCEDRIN MIGRAINE- acetaminophen, aspirin (nsaid) and caffeine tablet, film coated**

**Haleon US Holdings LLC**

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**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<sup>®</sup>**

**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**

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See new warnings information

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## MIGRAINE

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Pain Reliever/Pain Reliever Aid

24  
CAPLETS\*

\*CAPSULE-SHAPED TABLETS



### 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
<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>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>HYDROXYPROPYL CELLULOSE (1600000 WAMW)</b> (UNII: RFW2ET671P)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	

**PROPYLENE GLYCOL** (UNII: 6DC9Q167V3)

**SORBITAN MONOLAURATE** (UNII: 6W9PS8B71J)

**STEARIC ACID** (UNII: 4ELV7Z65AP)

**TITANIUM DIOXIDE** (UNII: 15FIX9V2JP)

### Product Characteristics

<b>Color</b>	white (White)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (Capsule shaped tablet)	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### 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	

<b>12</b>		200 in 1 BOTTLE; Type 0: Not a Combination Product		
<b>13</b>	NDC:0067-2039-77	1 in 1 CARTON	02/15/2010	
<b>13</b>		250 in 1 BOTTLE; Type 0: Not a Combination Product		
<b>14</b>	NDC:0067-2039-07	250 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2010	12/31/2012
<b>15</b>	NDC:0067-2039-33	1 in 1 CARTON	02/15/2010	
<b>15</b>		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: 4/2024

Haleon US Holdings LLC