

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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EXCEDRIN MIGRAINE RELIEF

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

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 |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M013 | 01/01/2024 | |

Labeler - Haleon US Holdings LLC (079944263)

Revised: 4/2024

Haleon US Holdings LLC