EXCEDRIN EXTRA STRENGTH PAIN RELIEVER- acetaminophen, aspirin (nsaid), and caffeine tablet, film coated
Haleon US Holdings LLC

Drug Facts

Active ingredient (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

Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - a cold
  - arthritis
  - muscular aches
  - toothache
  - premenstrual & menstrual cramps

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 8 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

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 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

Ask a doctor or pharmacist before use if you are taking

- a prescription drug for diabetes, gout, or arthritis
- any other drug, or are under a doctor’s care for any serious condition

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

- ringing in the ears or loss of hearing occurs
- painful area is red or swollen
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- any new symptoms occur

These could be signs of a serious condition

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**
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 caplets every 6 hours; not more than 8 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- store at 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?

1-800-452-0051

Principal Display Panel

NDC 0067-2001-05

EXCEDRIN

EXTRA STRENGTH

Acetaminophen, Aspirin (NSAID) and Caffeine

Pain Reliever/Pain Reliever Aid

100*CAPLETS*

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

62000000032208

EXCEDRIN EXTRA STRENGTH PAIN RELIEVER

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

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0067-2001
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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SORBITAN MONOLAURATE (UNII: 6W9PS8B71J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	

Product Characteristics

Color	white (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:0067-2001-05	1 in 1 CARTON	03/15/2019	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0067-2001-08	1 in 1 CARTON	03/15/2019	
2		300 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0067-2001-02	1 in 1 CARTON	09/30/2020	
3		24 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0067-2001-03	1 in 1 CARTON	09/30/2020	
4		30 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0067-2001-04	1 in 1 CARTON	09/30/2020	
5		50 in 1 BOTTLE; Type 0: Not a Combination Product		
	NDC:0067-2001			

6	NDC:0067-2001-06	1 in 1 CARTON	09/30/2020	
6		125 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:0067-2001-07	1 in 1 CARTON	09/30/2020	
7		200 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:0067-2001-09	1 in 1 CARTON	09/30/2020	
8		250 in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:0067-2001-01	2 in 1 POUCH; Type 0: Not a Combination Product	01/31/2021	
10	NDC:0067-2001-14	1 in 1 BLISTER PACK	01/31/2021	
10		8 in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	03/15/2019	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 4/2024 Haleon US Holdings LLC