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

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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

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 0067-2000-10

EXCEDRIN®

EXTRA STRENGTH

Acetaminophen, Aspirin (NSAID) and Caffeine

Pain Reliever/Pain Reliever Aid

10 *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

Visit us at www.excedrin.com

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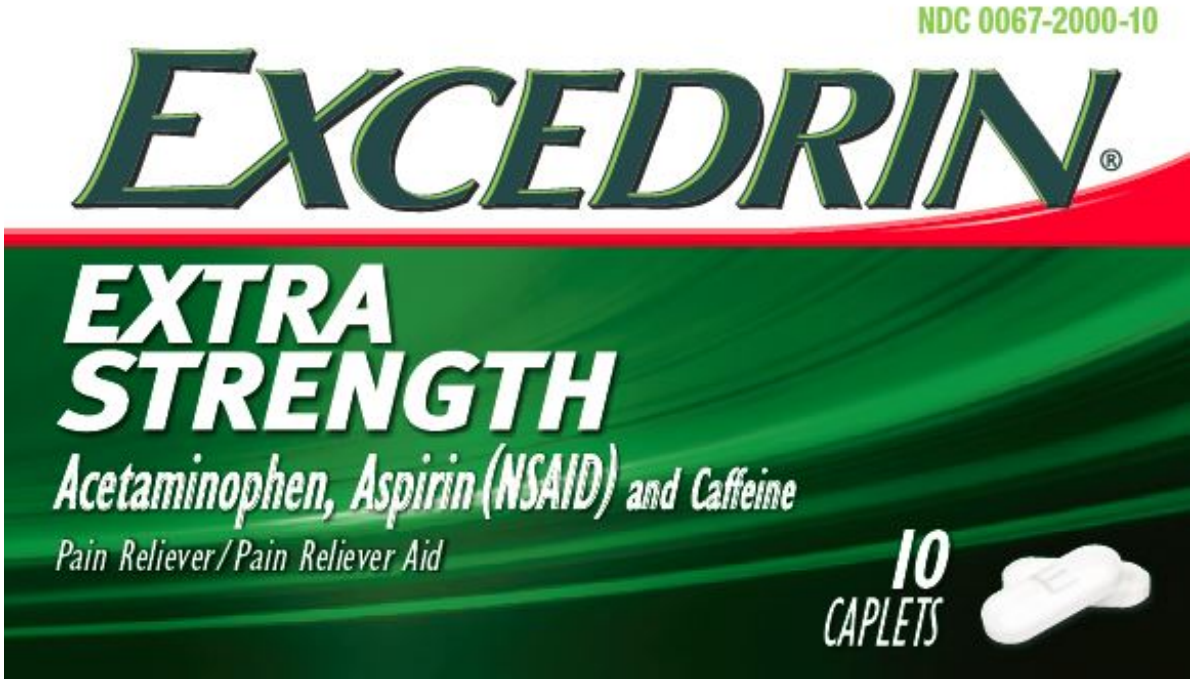

EXCEDRIN EXTRA STRENGTH PAIN RELIEVER

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

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0067-2000
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, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
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**	E
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-2000-02	2 in 1 POUCH; Type 0: Not a Combination Product	09/27/2006	
2	NDC:0067-2000-10	1 in 1 CARTON	09/27/2006	
2		10 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0067-2000-24	1 in 1 CARTON	09/27/2006	
3		24 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0067-2000-30	1 in 1 CARTON	09/27/2006	
4		30 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0067-2000-50	1 in 1 CARTON	09/27/2006	
5		50 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:0067-2000-91	1 in 1 CARTON	09/27/2006	
6		100 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:0067-2000-94	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/27/2006	12/31/2014
8	NDC:0067-2000-83	1 in 1 CARTON	09/27/2006	
8		125 in 1 BOTTLE; Type 0: Not a Combination		

8		Product		
9	NDC:0067-2000-20	1 in 1 CARTON	09/27/2006	
9		200 in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:0067-2000-77	1 in 1 CARTON	09/27/2006	
10		250 in 1 BOTTLE; Type 0: Not a Combination Product		
11	NDC:0067-2000-07	250 in 1 BOTTLE; Type 0: Not a Combination Product	09/27/2006	12/31/2014
12	NDC:0067-2000-33	1 in 1 CARTON	09/27/2006	
12		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
OTC monograph not final	part343	09/27/2006	

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 5/2023 GlaxoSmithKline Consumer Healthcare Holdings (US) LLC