

EXCEDRIN EXTRA STRENGTH- acetaminophen, aspirin (nsaid), and caffeine tablet, film coated
Select Corporation

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.

Excedrin® Extra Strength

Drug Facts

Active ingredients (in each caplet)	Purposes
Acetaminophen 250 mg	Pain reliever
Aspirin 250 mg (NSAID*)	Pain reliever
Caffeine 65 mg	Pain reliever aid

* nonsteroidal anti-inflammatory drug

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 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 care 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 of age and over	take 2 caplets every 6 hours; not more than 8 caplets in 24 hours
under 12 years	ask a doctor

Other information

- store at 20°-25°C (68°-77°F)
- read all product information before using. Keep this card 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

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Select Corporation

Carrollton, TX 75007

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GSK Consumer Healthcare, Warren, NJ 07059

PRINCIPAL DISPLAY PANEL - 2 Caplet Pouch Packet

EXCEDRIN®

EXTRA

STRENGTH

Acetaminophen, Aspirin (NSAID) and Caffeine


Pain Reliever/Pain Reliever Aid

1 Packet of 2 Caplets

EXCEDRIN[®]

EXTRA STRENGTH

Acetaminophen, Aspirin (NSAID) and Caffeine
Pain Reliever / Pain Reliever Aid

 1 Packet of 2 Caplets

Open Flap for DRUG FACTS



Read all warnings and directions before use

EXCEDRIN[®]

EXTRA STRENGTH



Single - Pack: 2 Caplets

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Corporation

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(800) 452-0051
Visit us at www.excedrin.com

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TAMPER EVIDENT PACKET. DO NOT USE IF SEAL IS BROKEN.

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Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: • skin reddening • blisters • rash
if 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

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- are age 60 or older



Drug Facts (continued)

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Stop use and ask a doctor if

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- you experience any of the following signs of stomach bleeding:
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**Drug Facts (continued)**

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Questions or comments? 1-800-452-0051

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1611868039

EXCEDRIN EXTRA STRENGTH

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52904-868(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)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
hydroxypropyl cellulose, unspecified (UNII: 9XZ8H6N6OH)	
hypromellose, unspecified (UNII: 3NXW29V3WO)	
light mineral oil (UNII: N6K5787QVP)	
microcrystalline cellulose (UNII: OP1R32D61U)	
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:52904-868-04	1 in 1 BLISTER PACK	01/23/2016	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:52904-868-05	2 in 1 BLISTER PACK	01/23/2016	
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:52904-868-25	25 in 1 CARTON	01/23/2016	
3		2 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:52904-868-50	50 in 1 CARTON	01/23/2016	
4		2 in 1 POUCH; 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	01/23/2016	

Labeler - Select Corporation (053805599)