EXCEDRIN EXTRA STRENGTH- acetaminophen, aspirin (nsaid), and caffeine tablet, film coated
State of Florida DOH Central Pharmacy

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 tablet)

Acetaminophen 250 mg

Aspirin 250 mg (NSAID)*

Caffeine 65 mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Pain reliever

Pain reliever aid

Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - a cold
  - arthritis
  - muscular aches
  - sinusitis
  - 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:

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 tables 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 a nonsteroidal anti-inflammatory drug (NSAID), which may cause 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 an NSAID (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 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 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
- high blood pressure
- you have asthma

Ask a doctor or pharmacist before use

- any other drug containing an NSAID (prescription or nonprescription)
- a blood thinning (anticoagulant) or steroid drug
- 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 doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs os 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 appear

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

Overdose Warning

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

Other information

- store at controlled room temperature 20^0 - 25^0 C (68^0 - 77^0 F)
- read all product information before using. Keep this box for important information

Inactive ingredients

benzoic acid, carnauba wax, FD&C blue #1, hydroxypropyl cellulose, 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

This product is supplied by **State of Florida DOH Central Pharmacy** as follows:

NDC	Strength	Quantity/Form	Color	Source Prod. Code
53808-0834-1	250 mg / 250 mg / 65 mg	30 Tablets in a Blister Pack	White	0067-2030

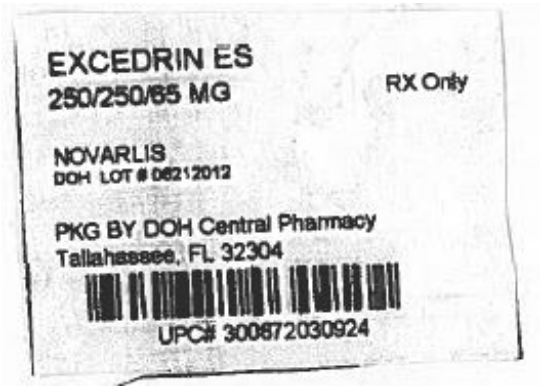
This product was Manufactured By:

Novartis Pharmaceuticals Corporation
One Health Plaza

And Repackaged By:

State of Florida DOH Central Pharmacy
104-2 Hamilton Park Drive
Tallahassee, FL 32304
United States

Principal Display Panel



EXCEDRIN EXTRA STRENGTH

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

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53808-0834(NDC:0067-2030)
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)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
DIMETHICONE 410 (UNII: TYU5GP6XGE)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	

LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN MONOLAURATE (UNII: 6W9PS8B71J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (White)	**Score**	no score
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	E
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53808-0834-1	30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	01/01/2013	

Labeler - State of Florida DOH Central Pharmacy (829348114)

Establishment

Name	Address	ID/FEI	Business Operations
State of Florida DOH Central Pharmacy		829348114	repack(53808-0834)

Revised: 9/2013 State of Florida DOH Central Pharmacy