

**EXCEDRIN EXTRA STRENGTH PAIN RELIEVER- acetaminophen, aspirin, and caffeine tablet, film coated**  
**Lil' Drug Store Products, Inc.**

*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.*

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**EXCEDRIN EXTRA STRENGTH PAIN RELIEVER**

**Drug Facts**

<b>Active ingredients (in each caplet)</b>	<b>Purposes</b>
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 and 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 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**
- 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
- Children under 12 years: ask a doctor

**Other information**

- store at 20°-25°C (68°-77°F)
- 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?**

**1-800-468-7746**

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**GSK Consumer Healthcare**, Warren, NJ 07059

## **PRINCIPAL DISPLAY PANEL - 2 Caplet Packet Box**

EXCEDRIN  
EXTRA  
STRENGTH

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

25 PACKETS of 2 CAPLETS EACH

***EXCEDRIN***

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



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***EXTRA  
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Pain Reliever / Pain Reliever Aid*



**25 PACKETS of 2 CAPLETS EACH**



# EXCEDRIN

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

25 PACKETS of 2 CAPLETS EACH

TAMPER EVIDENT PACKET. DO NOT USE IF SEAL IS BROKEN

## Drug Facts

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### Uses

- temporarily relieves minor aches and pains due to:
  - headache
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  - arthritis
  - muscular aches
  - toothache
  - premenstrual and 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 redness
- blister
- 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)
- stomach

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- you are taking a diuretic
- you have asthma

Date Stamp Area  
 No Varnish

## Drug Facts (continued)

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
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  - fever gets worse or lasts for more than 3 days
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- read all product information before using. Keep this box for important information.

### Inactive ingredients

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### Questions? 1-800-468-7746

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1-800-468-7746

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# EXCEDRIN EXTRA STRENGTH PAIN RELIEVER

acetaminophen, aspirin, and caffeine tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:29485-8026
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
<b>CAFFEINE</b> (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>HYDROXYPROPYL CELLULOSE, UNSPECIFIED</b> (UNII: 9XZ8H6N6OH)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>SORBITAN MONOLAURATE</b> (UNII: 6W9PS8B71J)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	E
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29485-8026-2	25 in 1 BOX	09/12/2020	
1		2 in 1 POUCH; Type 0: Not a Combination Product		

2	NDC:29485-8026-1	1 in 1 BLISTER PACK	06/17/2016	12/31/2024
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:29485-8026-4	2 in 1 BLISTER PACK	02/08/2016	12/31/2024
3		2 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:29485-8026-5	2 in 1 CARTON	10/05/2016	12/31/2024
4		2 in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:29485-8026-3	3 in 1 BLISTER PACK	06/15/2016	12/31/2024
5		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 final	M013	09/27/2006	12/31/2024

**Labeler** - Lil' Drug Store Products, Inc. (093103646)

Revised: 7/2023

Lil' Drug Store Products, Inc.