

**EXCEDRIN MIGRAINE, TRAVEL BASIX- acetaminophen, aspirin, and caffeine tablet, film coated**  
**EXCEDRIN MIGRAINE, CVP HEALTH- acetaminophen, aspirin, and caffeine tablet, film coated**  
**EXCEDRIN MIGRAINE- acetaminophen, aspirin, and caffeine tablet, film coated**  
**Lil' Drug Store Products, Inc.**

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**Excedrin<sup>®</sup> Migraine**  
**Lil' Drug Store<sup>®</sup>, TRAVEL BASIX, CVP<sup>®</sup> HEALTH**

### ***Drug Facts***

<b><i>Active ingredients (in each caplet)</i></b>	<b><i>Purposes</i></b>
Acetaminophen 250 mg	Pain reliever
Aspirin 250 mg (NSAID *)	Pain reliever
Caffeine 65 mg	Pain reliever aid

\* nonsteroidal anti-inflammatory drug

### **Use**

- treats migraine

### **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 2 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

### **Medication overuse headache warning**

Headaches may worsen if this product is used for 10 or more days per month.

### **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 never had migraines diagnosed by a health professional
- you have a headache that is different from your usual migraines
- you have the worst headache of your life
- you have fever and stiff neck
- you have headaches beginning after or caused by head injury, exertion, coughing or bending
- you experienced your first headache after the age of 50
- you have daily headaches
- you have a migraine so severe as to require bed rest

- 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
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have vomiting with your migraine headache

**Ask a doctor or pharmacist before use if you are**

- taking a prescription drug for:
  - diabetes
  - gout
  - arthritis
- under a doctor's care for any serious condition
- taking any other drug
- taking any other product that contains aspirin, acetaminophen, or any other pain reliever/fever reducer

**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
- your migraine is not relieved or worsens after first dose
- new or unexpected symptoms occur
- ringing in the ears or loss of hearing occurs

**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**
- adults: take 2 caplets with a glass of water
- if symptoms persist or worsen, ask your doctor
- do not take more than 2 caplets in 24 hours, unless directed by a doctor
- under 18 years of age: ask a doctor





# Pain Reliever/Pain Reliever Aid

[caplets image]

4

Caplets\* Total

\*CAPSULE-SHAPED TABLETS

(2) 2ct PACKETS

[CVP® HEALTH logo]



## EXCEDRIN MIGRAINE, TRAVEL BASIX acetaminophen, aspirin, and caffeine tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-6449
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		Strength
Ingredient Name		
BENZOIC ACID (UNII: 8SKN0B0MIM)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)		

<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>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 (Capsule shaped tablet)	<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:66715-6449-3	2 in 1 CARTON	11/29/2022	
1		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
NDA	NDA020802	11/29/2022	

## EXCEDRIN MIGRAINE, CVP HEALTH

acetaminophen, aspirin, and caffeine tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66715-6549
<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 (160000 WAMW)</b> (UNII: RFW2ET671P)	
<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>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 (Capsule shaped tablet)	<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:66715-6549-2	3 in 1 CARTON	05/06/2022	
1		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
NDA	NDA020802	05/06/2022	

## EXCEDRIN MIGRAINE

acetaminophen, aspirin, and caffeine tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66715-9749
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<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)	
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<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL (Capsule shaped tablet)	<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:66715-9749-3	3 in 1 CARTON	08/15/2019	
1		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
NDA	NDA020802	08/15/2019	

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