

**EXCEDRIN MIGRAINE- acetaminophen, aspirin (nsaid) and caffeine tablet, film coated**  
**Jones Contract Packaging Services**

*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 Migraine**

**Active ingredients (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

**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

**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 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

### ***Other information***

- store at controlled room temperature 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?***

**1-800-468-7746**

### **Package Labeling**

NDC 0067-2039-02  
**EXCEDRIN**

**MIGRAINE**

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

2 CAPLETS

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Pain reliever  
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\*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 **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

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LINE AND TEAR AT SLIT  
DO NOT USE IF SEAL IS BROKEN

TO OPEN: FOLD ALONG DOTTED  
TAMPER EVIDENT PACKET

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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 **Other information** • store at room temperature 20°-25°C (68°-77°F) • read all product information before using.  
**Inactive ingredients** benzoic acid, camauba 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 Dist by: GSK Consumer Healthcare, Warren, NJ 07059 ©2015 GSK or its licensor. 12602



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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 **Other information** • store at room temperature 20°-25°C (68°-77°F) • read all product information before using.  
**Inactive ingredients** benzoic acid, camauba 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 Dist by: GSK Consumer Healthcare, Warren, NJ 07059 ©2015 GSK or its licensor. 12602



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**EXCEDRIN MIGRAINE**

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

**Product Information**

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:67414-239

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)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
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	CAPSULE (Capsule shaped tablet)	Size	18mm
Flavor		Imprint Code	E
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67414-239-02	2000 in 1 BOX	01/24/2018	
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
OTC monograph not final	part343	01/24/2018	

**Labeler** - Jones Contract Packaging Services (243697187)**Registrant** - Jones Contract Packaging Services (243697187)**Establishment**

Name	Address	ID/FEI	Business Operations
Jones Contract Packaging Services		243697187	pack(67414-239)

Revised: 12/2019

Jones Contract Packaging Services