

EXCEDRIN MIGRAINE- acetaminophen, aspirin, and caffeine tablet, film coated
Select Corporation

Excedrin® Migraine

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

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 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	<ul style="list-style-type: none"> • 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)
- 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**

Repackaged and Distributed by:
Select Corporation Carrollton, TX 75007

PRINCIPAL DISPLAY PANEL - 1 Caplet Pouch Blister Pack

EXCEDRIN®

MIGRAINE

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

CAPLETS*

*CAPSULE-SHAPED TABLETS

1 Packet of 2 Caplets

Drug Facts (continued)

adults	<ul style="list-style-type: none"> 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

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

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EXCEDRIN
MIGRAINE
CAPLETS[®]
ORANGE-GRAPE TABLETS

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
MIGRAINE

6 55708 11871 9

Single - Pack: 2 Caplets

Repackaged and Distributed by:
Select Corporation
 Carrollton, TX 75007

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

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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

Drug Facts (continued)

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- you are taking a diuretic
- you have asthma
- you have problems or serious side effects from taking pain relievers or fever reducers

Drug Facts (continued)

- you have vomiting with your migraines headache

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- 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

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Directions

- do not use more than directed

1611871039

EXCEDRIN MIGRAINE

acetaminophen, aspirin, and caffeine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52904-871(NDC:0067-2040)
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
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Inactive Ingredients

Ingredient Name	Strength
benzoic acid (UNII: 8SKN0B0MIM)	
carnauba wax (UNII: R12CBM0EIZ)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
hypromellose, unspecified (UNII: 3NXW29V3WO)	
light mineral oil (UNII: N6K5787QVP)	
hydroxypropyl cellulose, unspecified (UNII: 9XZ8H6N6OH)	
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	Score	no score
Shape	CAPSULE	Size	16mm
Flavor		Imprint Code	E
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52904-871-04	1 in 1 BLISTER PACK	09/09/2012	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:52904-871-05	2 in 1 BLISTER PACK	09/09/2012	
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:52904-871-25	25 in 1 CARTON	09/09/2012	
3		2 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:52904-871-50	50 in 1 CARTON	09/09/2012	
4		2 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
NDA	NDA020802	09/09/2012	

Labeler - Select Corporation (053805599)

Revised: 4/2022

Select Corporation