

SOUND BODY MIGRAINE RELIEF- acetaminophen, aspirin, caffeine tablet, film coated

Big Lots Stores, Inc.

Big Lots, Inc Migraine Relief Drug Facts

Active ingredients (in each caplet)

Acetaminophen 250 mg

Aspirin 250 mg (NSAID*)

Caffeine 65 mg

*nonsteroidal anti-inflammatory drug

Purposes

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

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 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. (1-800-222-1222) 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 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

carnauba wax, crospovidone, FD&C blue #1 aluminum lake, hypromellose, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, saccharin sodium, stearic acid, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

SOUNDBODY™

Compare to the Active Ingredients in Excedrin® Migraine Caplets

Migraine Relief

Acetaminophen/Aspirin (NSAID)/Caffeine Tablets

Pain Reliever/Pain Reliever Aid

24 COATED CAPLETS**

**CAPSULE-SHAPED TABLETS

Actual Size

† This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Excedrin® Migraine Caplets.



Drug Facts

Active ingredients (in each caplet) **Pain Relievers**
 Acetaminophen 250 mg, Aspirin 250 mg (NSAID)[†], Caffeine 65 mg (NSAID)[†], and other inactive ingredients. Pain reliever aid, nonsteroidal anti-inflammatory drug.

Use ● treats migraine

Warnings
 Rey's syndrome: Children and teenagers who have or are recovering from chickenpox or flu-like symptoms should not use this product. When using this product, if it changes the way you eat and vomiting occur, consult a doctor because these symptoms could be an early sign of Rey's syndrome, a rare but serious illness.
 Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ● skin redness ● blisters ● rash ● itchy skin ● hives ● facial swelling ● asthma like wheezing ● stroke
 Allergy alert: Aspirin may cause a severe allergic reaction which may include: ● hives ● facial swelling ● asthma like wheezing ● stroke
 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 aspirin or nonsteroidal 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 overdose headache warning: Headaches may worsen if the 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 products, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally rapid heart beat.

Drug Facts (continued)

Don't 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 migraine diagnosed by health professional ● you have had severe headache or you have had severe dizziness, fainting, or vomiting ● you have had heart trouble or you have had heart failure, angina, or you have had a heart attack ● you have had a stroke ● you have had a seizure ● you have had a kidney problem ● you have had a liver problem ● you have had a stomach problem, such as heartburn ● you have had high blood pressure, heart disease, low blood sugar, or kidney disease ● you are taking a diuretic ● you have asthma ● you have problems or serious side effects from taking pain reliever or fever reducers ● you have vomiting with you migraine headache.
 Ask a doctor or pharmacist before use if you are: ● taking a prescription drug for: ● diabetes ● gout ● arthritis ● and/or a doctor's care for any serious condition ● taking many 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: ● black, tarry or bloody stool ● vomit blood ● vomit that looks like coffee grounds ● you have stomach pain that does not get better ● your urine is dark ● you have black or tarry stools ● you have a new or worse heartburn ● you have a new or worse headache ● you have a new or worse dizziness ● you have a new or worse ringing in the ears or loss of hearing occurs.
 If you experience heart failure, ask a health professional for use. It is especially important not to use aspirin at 20 weeks or later in pregnancy unless directed by a doctor. Do not use aspirin 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. (1-800-222-1222.) Usual medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.



KEEP BOX FOR REFERENCE

GLUTEN FREE

DO NOT USE IF PRINTED FOIL UNDER CAP IS BROKEN OR MISSING

ACTUAL SIZE



Compare to the Active Ingredients in Excedrin® Migraine Caplets†

Migraine Relief

Acetaminophen/Aspirin (NSAID)/
 Caffeine Tablets
 Pain Reliever/Pain Reliever Aid

24 COATED CAPLETS** **CAPSULE-SHAPED TABLETS

Actual Size

Drug Facts (continued)
Directions ● do not use more or 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, which is the maximum daily amount ● with other drugs containing acetaminophen ● 3 or more alcoholic drinks every day while using this product ● take more or for a longer time than directed.
Other information ● store at 20°-25°C (68°-77°F) ● use caplets after the expiration date ● do not use if the caplet is broken or if the caplet is not in its original packaging ● keep out of reach of children.
Keep this and all other medications away from children. ● if you experience any of the following signs of stomach bleeding: ● black, tarry or bloody stool ● vomit blood ● vomit that looks like coffee grounds ● you have stomach pain that does not get better ● your urine is dark ● you have black or tarry stools ● you have a new or worse heartburn ● you have a new or worse headache ● you have a new or worse dizziness ● you have a new or worse ringing in the ears or loss of hearing occurs.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222.) Usual medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

Questions or comments? 1-800-719-9260
 Package by Perfego Company for:
 Big Lots Stores, Inc.
 P.O. Box 28523
 Columbus, OH 43228-0523 #5003185 ITEM#37462

SOUND BODY MIGRAINE RELIEF
 acetaminophen, aspirin, caffeine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50594-374
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	L374
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50594-374-62	1 in 1 CARTON	07/30/2020	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075794	07/30/2020	

Labeler - Big Lots Stores, Inc. (017885351)

