

MIGRAINE FORMULA- acetaminophen, aspirin, caffeine tablet, film coated
HyVee Inc

Hy-Vee, Inc. Migraine Formula 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 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?

1-800-289-8343

Principal Display Panel

HyVee®

Compare to Excedrin® Migraine Relief Active Ingredients

Migraine Formula

Acetaminophen 250 mg/Aspirin 250 mg (NSAID)/Caffeine 65 mg Tablets

Pain Reliever/Pain Reliever Aid

actual size

24 COATED CAPLETS**

**Capsule-Shaped Tablets

37462 2H C10



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

Drug Facts

Active ingredients (in each caplet) **Purposes**
 Acetaminophen 250 mg, Aspirin 250 mg (NSAID), Caffeine 65 mg

Pain reliever
 Pain reliever
 Pain reliever and
 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. **Always 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 (wheezy) ■ shock

Low warnings: 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 a very 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 alcohol drinking (including beer, distilled drug ■ take other drugs containing prescription or nonprescription (Aspirin, ibuprofen, naproxen, or others)

Drug Facts (continued)

■ 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 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 the disease

■ stomach bleeding warning applies to you ■ you have a history of stomach problems, such as the ulcers, ulcers, or kidney disease ■ you are taking a diuretic ■ you have high blood pressure, heart disease, liver cirrhosis, or kidney disease ■ you have problems or serious side effects from taking pain relievers or fever reducers ■ you have vomiting with your migraine headache

Drug Facts (continued)

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 16 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.

Drug Facts (continued)
 ■ active ingredients: carnauba wax, croscollon, FD&C blue #1, titanium dioxide, hypromellose, methylcroscellulose, polydextrose, polyethylene glycol, saccharin sodium, stearic acid, titanium dioxide

Questions or comments? 1-800-289-8343

***This product is not manufactured or distributed by Hebron CH SAPI, owner of the registered trademark Excedrin®. DISTRIBUTED BY HY-VEE, INC. WEST DES MOINES, IA 50266 PERA11025 http://hy-vee.com/info/RdP.htm SATISFACTORY GUARANTEE. CALL 1-800-289-8343 www.hy-vee.com

Hy-Vee
 NDC 42507-374-62

Migraine Formula
 Acetaminophen 250 mg/Aspirin 250 mg (NSAID)/
 Caffeine 65 mg Tablets
 Pain Reliever/Pain Reliever Aid

***Compare To Excedrin® Migraine Relief Active Ingredients

actual size

24 COATED CAPLETS**

**Capsule-Shaped Tablets

MIGRAINE FORMULA
 acetaminophen, aspirin, caffeine tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42507-374
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, UNSPECIFIED (UNII: 2S7830E561)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
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	CAPSULE	Size	17mm
Flavor		Imprint Code	L374
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42507-374-62	1 in 1 CARTON	09/09/2002	
1	NDC:42507-374-24	24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:42507-374-78	1 in 1 CARTON	09/09/2002	
2	NDC:42507-374-00	100 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	09/09/2002	

Labeler - HyVee Inc (006925671)

