TOPCARE MIGRAINE FORMULA- acetaminophen, aspirin, caffeine tablet Topco Associates LLC

Topco Associates LLC. 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

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. (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?

Principal Display Panel

WITH CAFFEINE

Migraine Formula

ACETAMINOPHEN / ASPIRIN (NSAID) / CAFFEINE TABLETS, USP

Pain Reliever / Pain Reliever Aid

COMPARE TO EXCEDRIN® MIGRAINE active ingredients

actual size

100 COATED CAPLETS†

†CAPSULE-SHAPED TABLETS



KEEP BOX FOR REFERENCE

'This product is not ma nufactured or distr buted by Novartis Consum er Health, Inc., distr butor of Excedrin® Migraine.



DISTRIBUTED BY TOPC O ASSOCIATES LLC

E.K.GROVE VILLAGE, IL 60007

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to pocare@to pco.com www.topca.rebrand.com

Drug Facts (continued)

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Drug Facts (continued)

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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? 1-888-423-0139





EXP.

: 37478 88 CLO

TOPCARE MIGRAINE FORMULA

acetaminophen, aspirin, caffeine tablet

Product Information	luct Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-374	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	250 mg	
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg	
CAFFEINE (UNII: 3G6 A5W338 E) (CAFFEINE - UNII:3G6 A5W338 E)	CAFFEINE	65 mg	

Inactive Ingredients			
Ingredient Name	Strength		
CARNAUBA WAX (UNII: R12CBM0EIZ)			
CROSPO VIDO NE (15 MPA.S AT 5%) (UNII: 68401960 MK)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)			
PO VIDO NE (UNII: FZ989GH94E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			

Product Characteristic	uct Characteristics		
Color	WHITE	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	L374

Contains

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:36800-374-62	1 in 1 CARTON	04/01/2003		
1		24 in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:36800-374-78	1 in 1 CARTON	04/01/2003		
2		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	04/01/2003		

Labeler - Topco Associates LLC (006935977)

Revised: 12/2019 Topco Associates LLC