

ACETAMINOPHEN, ASPIRIN AND CAFFEINE- acetaminophen, aspirin and caffeine tablet
Safrel Pharmaceuticals, LLC.

Acetaminophen, Aspirin and Caffeine Tablets USP, 250 mg, 250 mg and 65 mg

ACTIVE INGREDIENT(S)

Acetaminophen 250 mg

Aspirin 250 mg (NSAID*)

Caffeine 65 mg

*nonsteroidal anti-inflammatory drug

PURPOSE

Pain reliever

Pain reliever

Pain reliever aid

USE(S)

- 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

- taking a prescription drug for:
 - o diabetes
 - o gout
 - o 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 DOCTOR IF

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding :
 - o feel faint
 - o vomit blood
 - o have bloody or black stools
 - o 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° to 25°C (68° to 77°F)

- close cap tightly after use
- read all product information before using. Keep this box for important information.
- **Tamper Evident : Do not use if foil inner seal under the cap is opened or missing**

INACTIVE INGREDIENTS

Carnauba wax, hydroxypropyl cellulose, hypromellose, microcrystalline cellulose, propylene glycol, sodium stearyl fumarate and titanium dioxide




QUESTIONS OR COMMENTS?

Contact 1-844-384-3273 Mon-Fri 8:00 AM EST to 5:00 PM PST

Distributed By:

Safrel Pharmaceuticals, LLC
Bridgewater, NJ 08807

PRINCIPAL DISPLAY PANEL

 <p>NDC 71309-079-03 *Compare to Excedrin Migraine* Extra Strength active ingredient</p> <p>MIGRAINE HEADACHE RELIEF</p> <p>Pain Reliever / Fever Reducer</p> <p>Acetaminophen 250mg each caplet Aspirin 250mg (NSAID) each caplet Caffeine 65 mg each caplet</p> <p>300 CAPLETS </p>	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active Ingredient (in each caplet)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Acetaminophen 250 mg</td> <td>Pain reliever</td> </tr> <tr> <td>Aspirin 250 mg (NSAID)*</td> <td>Pain reliever</td> </tr> <tr> <td>Caffeine 65 mg</td> <td>Pain reliever aid</td> </tr> </tbody> </table> <p>*non-steroidal anti-inflammatory drug</p> <p>Uses</p> <ul style="list-style-type: none"> ■ treats migraine <p>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.</p> <p>Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blister ■ rash. Aspirin may cause severe allergic reaction ■ hives, ■ facial swelling ■ asthma. ■ shock. If a skin reaction occurs, stop use and seek medical help right away.</p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 8 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.</p> <p>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 heartbeat.</p> <p>Stomach bleeding warning: ■ This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chances are higher if you: ■ have had stomach ulcers or bleeding problems ■ are age 60 or older ■ take a blood thinning</p>	Active Ingredient (in each caplet)	Purpose	Acetaminophen 250 mg	Pain reliever	Aspirin 250 mg (NSAID)*	Pain reliever	Caffeine 65 mg	Pain reliever aid	<p>Drug Facts (Continued)</p> <p>(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. ■ take more or for a longer time than directed.</p> <p>Do not use ■ if you are allergic to acetaminophen ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</p> <p>Ask a doctor before use if 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 have asthma ■ you are taking a diuretic</p> <p>Ask a doctor or pharmacist before use if you are ■ taking a prescription drug for diabetes, gout, or arthritis ■ taking any other drug or are under a doctor's care for any serious condition</p> <p>Stop use and ask a doctor if ■ you experience any of the following signs of stomach bleeding: ■ feel faint ■ have bloody or black stools ■ vomit blood ■ have a stomach pain that does not get better ■ an allergic ■ reaction occurs. Seek medical help right away. ■ any new symptoms appear ■ symptoms do not get better or worsen ■ painful area is red or swollen ■ pain ■ pain gets worse or lasts for more than 10 days ■ fever gets worse or lasts for more than 3 days</p> <p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p>	<p>Drug Facts (Continued)</p> <p>Directions</p> <ul style="list-style-type: none"> ■ do not use more than directed ■ adults and children 12 years and over: take 2 caplets every 6 hours; not more than 8 caplets in 24 hours ■ children under 12 years: ask a doctor <p>Other Information</p> <ul style="list-style-type: none"> ■ store at 20°-25°C (68°-77°F) ■ close cap tightly after use ■ read all product information before using. <p>Inactive Ingredients</p> <p>corn starch, croscopolvidone, hypromellose, microcrystalline cellulose, povidone, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide</p> <p>Questions & Comments? Call 1-844-384-3723</p> <p>DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING</p> <p>Distributed By: Safrel Pharmaceuticals Bridgewater, NJ 08807 USA www.safrel.com</p>  <p>3-71309-07903-6</p>
	Active Ingredient (in each caplet)	Purpose									
	Acetaminophen 250 mg	Pain reliever									
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Caffeine 65 mg	Pain reliever aid										

ACETAMINOPHEN, ASPIRIN AND CAFFEINE

acetaminophen, aspirin and caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71309-079
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
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE (Capsule shaped Tablet)	Size	17mm
Flavor		Imprint Code	l1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71309-079-03	300 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214039	04/15/2021	

Labeler - Safrel Pharmaceuticals, LLC. (080566287)

Revised: 11/2023

Safrel Pharmaceuticals, LLC.