

EXTRA STRENGTH HEADACHE RELIEF- extra strength headache relief tablet, coated
Safrel Pharmaceuticals, LLC.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Extra Strength Headache Relief

Drug Facts

Purpose

Pain reliever, Pain reliever aid

Active Ingredient (in each caplet)

Acetaminophen 250mg

Aspirin 250mg

Caffeine 65mg

Uses

- Temporarily relieves minor aches and pains due to:
- headache
- a cold
- arthritis
- muscular aches
- sinusitis
- toothache
- premenstrual and menstrual cramps

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 behaviour 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: Aspirin may cause a severe allergic reaction, which may include:

- hives
- shock
- facial swelling
- asthma (wheezing)

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 8 Tablets 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, food, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat.

Do not use

- if you 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 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

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

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 stomach pain that does not get better

- an allergic reaction occurs. Seek medical help right away.
- any new symptoms appear
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- painful area is red or swollen

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 (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.

Directions

- **Do not use more than directed**
- Drink a full glass of water with each dose
- Adults and children 12 years and over
- Take 2 tablets every 6 hours
- Do not take more than 8 tablets in 24 hours
- Children under 12 years: ask a doctor

Other Information

- Store at 25°C (77°F) excursions permitted between 15-30°C (59-86°F)
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

Inactive ingredients

- Corn starch
- Crospovidone
- Hypromellose
- Microcrystalline cellulose
- Povidone
- Propylene glycol
- Sodium Lauryl sulfate
- Sodium starch glycolate
- Stearic acid
- Titanium dioxide

Questions or comments?

Call toll free 1-844-384-3723 Monday through Friday 9AM- 5PM EST or www.safrel.com

Extra Strength Headache Relief

Acetaminophen 250mg / Pain Reliever

Aspirin 250mg (Nsaid) / Pain Reliever

Caffeine 65mg / Pain Reliever Aid

Compare to Excedrin® Extra Strength active ingredients

Distributed by:

Safrel Pharmaceuticals, LLC

Bridgewater, NJ 08807

www.safrel.com

Drug Facts

Active Ingredient (in each caplet) **Purpose**

Acetaminophen 250 mg Pain reliever

Aspirin 250 mg (NSAID)* Pain reliever

Caffeine 65 mg Pain reliever aid

*non-steroidal anti-inflammatory drug

Uses temporarily relieves minor aches and pains due to: headache a cold arthritis muscular aches sinusitis toothache premenstrual and menstrual cramps

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 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.

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.

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.

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

Drug Facts (Continued)

(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.

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.

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

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

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.

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.

Drug Facts (Continued)

Directions

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

Other Information

store at 20°-25°C (68°-77°F) close cap tightly after use

read all product information before using.

Inactive Ingredients

corn starch, croscopolone, hypromellose, microcrystalline cellulose, povidone, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide

Questions & Comments? Call 1-844-384-3723

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

Distributed By: Safrel Pharmaceuticals
Bridgewater, NJ 08807 USA
www.safrel.com

No Varnish Area

713091180312

EXTRA STRENGTH HEADACHE RELIEF

extra strength headache relief tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71309-118
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

Inactive Ingredients

Ingredient Name	Strength
CROSPROVIDONE (UNII: 2S7830E561)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71309-118-03	300 in 1 BOTTLE	04/01/2021	
1	NDC:71309-118-24	1 in 1 CARTON		
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
OTC monograph not final	part343	03/01/2021	

Labeler - Safrel Pharmaceuticals, LLC. (080566287)