

**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.*

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**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](http://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](http://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, croscopolidone, 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](http://www.safrel.com)

No Varnish Area

713091180312

## EXTRA STRENGTH HEADACHE RELIEF

extra strength headache relief tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71309-118
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
<b>CAFFEINE</b> (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65

### Inactive Ingredients

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

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### 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)