

**TENSION HEADACHE RELIEF- acetaminophen 500mg 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.

Tension Headache Relief

Drug Facts

Tension Headache Relief

Purpose

Pain reliever, Pain reliever aid

Active Ingredients (in each caplet)

Acetaminophen 500mg

Caffeine 65mg

Uses

Temporarily relief minor aches and pains due to:

- Headache
- Muscular aches

Warnings

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

- more than 6 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

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.

Do not Use

- with any other drug containing acetaminophen (prescription or nonprescription). Ask a doctor or pharmacist before using with other drugs if you are not sure.

Ask a doctor before use

- if you have liver disease

Ask a doctor or pharmacist

If you are taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- Any new symptoms appear
- Symptoms do not get better or worsen
- Painful area is red or swollen
- 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 overdosage, 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 exceed recommended dosage.
- Adults and children 12 years and over: Take 2 tablets every 6 hours; do not take more than 6 tablets in 24 hours
- Children under 12 years: Ask a doctor

Other Information

- Store at controlled room temperature 20°-25°C (68°-77°F)
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP

Inactive Ingredients

- Colloidal silicon dioxide
- Croscarmellose sodium
- D&C red # 27
- FD&C blue # 1
- FD&C yellow # 6
- Magnesium stearate
- Microcrystalline cellulose
- Polyethylene glycol
- Pregelatinized starch

- Polyvinyl pyrrolidone
- Stearic acid
- Talc
- Titanium dioxide

Questions or comments?

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

Tension Headache Relief

Acetaminophen 500mg

Caffeine 65mg

Compare to Excedrin® Tension Headache active ingredients Distributed by:

Safrel Pharmaceuticals, LLC
Bridgewater, NJ 08807

www.safrel.com

Safrel®
TENSION HEADACHE RELIEF
EXTRA STRENGTH
 Pain Reliever/Pain Reliever Aid
 Acetaminophen 500mg each caplet
 Caffeine 65 mg each caplet
 Aspirin Free
 200 Caplets

NDC 71309-105-02

Drug Facts
Active Ingredient (In each caplet) **Purpose**
 Acetaminophen 500 mg.....Pain reliever
 Caffeine 65 mg.....Pain reliever Aid
Uses temporarily relieves minor aches and pains due to:
 ■ headache ■ muscular aches
Warnings
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.
Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 6 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.
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 ■ Ask a doctor or pharmacist before use if you are ■ taking the blood thinning drug warfarin

Drug Facts (Continued)
Stop use and ask a doctor if occurs. Seek medical help right away.
 ■ any new symptoms appear
 ■ symptoms do not get better or worsen
 ■ painful area is red or swollen
 ■ 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 right away. **Diack 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 and children 12 years and over:** take 2 caplets every 6 hours; not more than 6 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
 colloidal silicon dioxide, croscarmellose sodium, D&C red #27, FD&C blue #1, FD&C yellow #6, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, polyvinyl pyrrolidone, stearic acid, talc, titanium dioxide

Drug Facts (Continued)
Questions & Comments?
 Call 1-844-384-3723
DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING
 Distributed by:
 Safrel Pharmaceuticals, LLC
 Bridgewater, NJ 08807
www.safrel.com

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No Varnish

TENSION HEADACHE RELIEF

acetaminophen 500mg tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71309-105
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71309-105-02	200 in 1 BOTTLE	03/01/2021	
1	NDC:71309-105-24	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)