# 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.

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

- Polyvinyl pyrolidone
- 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**

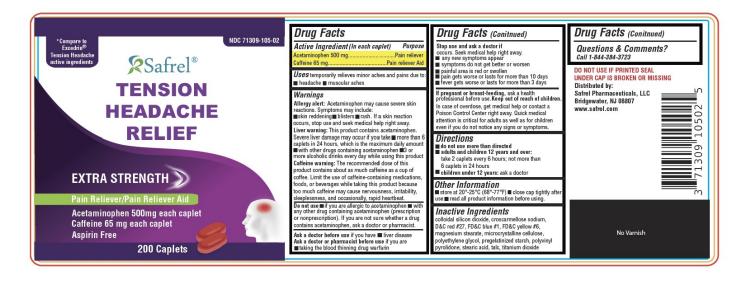
Acetaminophen 500mg

Caffeine 65mg

Compare to Excedrin® Tension Headache active ingredients Distributed by:

Safrel Pharmaceuticals, LLC Bridgewater, NJ 08807

www.safrle.com



# 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

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
<b>D&amp;C RED NO. 27</b> (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: FZ 989GH94E)		

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

P	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	
inidi			

# **Labeler -** Safrel Pharmaceuticals, LLC. (080566287)