

TENSION HEADACHE RELIEF- acetaminophen, caffeine tablet
Pioneer Life Sciences, LLC

Tension Headache Relief (Acetaminophen 500mg and caffeine 65mg)

Active Ingredients (in each caplet)

Acetaminophen 500mg
Caffeine 65 mg

Purpose

Acetaminophen
500mg.....Pain reliever
Caffeine 65mg.....
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 Doctor:

Ask a doctor before use if

- you have liver disease

ASK DOCTOR/PHARMACIST:

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin

Stop use and ask doctor if

- any new symptoms occur
- 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. These could be signs of a serious condition.

PREGNANCY

If pregnant or breast-feeding, ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN

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

- 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, F D & C yellow # 6, F D & C Blue # 2, Microcrystalline Cellulose, Magnesium Stearate, Polyethylene Glycol, Polyvinyl Pyrrolidone, Pregelatinized Starch, Polyvinyl Alcohol, Stearic Acid Powder, Titanium Dioxide, Talc.

QUESTIONS OR COMMENTS?

Call 1-732-698-5070 Monday through Friday 9AM to 5PM EST.

PRINCIPAL DISPLAY PANEL

TAMPER EVIDENT Do not use if safety seal under cap is broken or missing.

Drug Facts

Active Ingredients (in each caplet)
 Acetaminophen 500mg
 Caffeine 65mg

USES: Temporarily relieves minor aches and pain due to: ■ headaches ■ muscular aches

WARNINGS: ALLERGY ALERT: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ 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 ■ no more than 6 caplets in 24 hours, which is the maximum daily amount ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks everyday 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 ever had an allergic reaction 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 a liver disease.

Ask a doctor or pharmacist before use if you are: ■ taking the blood thinning drug warfarin.

Stop use and ask doctor if: ■ any new symptoms occur ■ 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. These could be signs of a serious condition. **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.

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

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QUESTIONS OR COMMENTS? Call 1-732-698-5070 Monday through Friday 9AM to 5PM EST.

This product is not manufactured or distributed by GSK Consumer Health, owner of the registered trademark EXCEDRIN® Tension Headache Caplets.

Distributed by: **GenCare Consumer Products, LLC**
 41E Collins Ln, Suite A, East Brunswick, NJ 08816

PL0108-00
 Lot No.
 Exp. Dt.

X002OST6VB

TENSION HEADACHE RELIEF

acetaminophen, caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72090-004
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
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CROSCARMELOSE SODIUM (UNII: M28OL1HH48)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)
TALC (UNII: 7SEV7J4R1U)
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
STARCH, CORN (UNII: O8232NY3SJ)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
D&C RED NO. 27 (UNII: 2LRS185U6K)
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)
MAGNESIUM STEARATE (UNII: 70097M6I30)
STEARIC ACID (UNII: 4ELV7Z65AP)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)

Product Characteristics

Color	red	Score	no score
Shape	CAPSULE (Capsule shape Tablet)	Size	28mm
Flavor		Imprint Code	None
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72090-004-02	200 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	08/03/2020	

Labeler - Pioneer Life Sciences, LLC (014092742)