

TENSION HEADACHE RELIEF- tension headache relief capsule, coated

Allegiant Health

GreenField - Tension Headache

Active ingredient(s)

Acetaminophen 500 mg
Caffeine 65mg

Purpose

Pain reliever
Pain reliever aid

Use(s)

temporarily relieves 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 8 tablets in 24 hours, which is the maximum daily amount ■ take with other drugs containing acetaminophen ■ have 3 or more alcoholic drinks every day while using this product

Allergy alert: Aspirin may cause a severe allergic reaction which may include:

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

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.

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 non-prescription). 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

Stop use and ask a 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/Breastfeeding

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.

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 8 caplets in 24 hours

Children under 12 years: ask a doctor

Other information

- Store at 20-25°C (68-77° F)
- Do not use if imprinted safety seal under cap is broken or missing

Inactive ingredients

corn starch, croscarmellose sodium, crospovidone, D&C red #27 aluminum lake, FD&C red #40

aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, silicon dioxide, stearic acid, titanium dioxide

Questions

1-888-952-0050 (Monday through Friday 9AM - 5PM EST)

Principal Display Panel

Well Fine Med US *COMPARED TO EXCEDRIN®
ACTIVE INGREDIENT

See New Warnings Information

TENSION HEADACHE RELIEF

ASPIRIN FREE

Acetaminophen & Caffeine
Pain Reliever/ Headache Reliever



24 Caplets

See carton for full product information

Drug Facts

Active Ingredients (in each caplet)

| | |
|----------------------|-------------------------|
| Acetaminophen 500 mg | Pain reliever |
| Caffeine 65mg | Pain reliever aid |

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 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.

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. 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 caplets every 6 hours. Do not take more than 8 caplets in 24 hours
Children under 12 years: ask a doctor

Manufactured For:
Well Fine Med US Pharmaceutical
Deser Park, NY 11729

Lot: LB1939
Exp: R0721

GreenShield
TEPHRA PHARMACEUTICAL GROUP, L.P. 6823
Made in USA

Tension Headache



Tension Headache

TENSION HEADACHE RELIEF
 tension headache relief capsule, coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69168-001 |
| 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 |
|------------------------------------------------------------|-----------------|
| STARCH, CORN (UNII: O8232NY3SJ) | |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| CROSPVIDONE (UNII: 2S7830E561) | |
| D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POVIDONE (UNII: FZ989GH94E) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|---------|---------------------|----------|
| Color | red | Score | no score |
| Shape | CAPSULE | Size | 17mm |
| Flavor | | Imprint Code | AZ 029 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---------------------------------------------------|-----------------------------|---------------------------|
| 1 | NDC:69168-001-24 | 1 in 1 CARTON | 11/22/2021 | |
| 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 Drug | M013 | 11/22/2021 | |

Labeler - Allegiant Health (079501930)

Revised: 11/2021

Allegiant Health