

TENSION HEADACHE RELIEF- acetaminophen, caffeine tablet
Hi-Tech Nutraceuticals, 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.

Active ingredients (in each caplet)	Purpose
Acetaminophen 500 mg	Pain reliever
Caffeine 65 mg	Pain reliever aid

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

Do not use:

- if you are allergic to acetaminophen
- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Keep out of reach of children.

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

Uses:

- temporarily relieves minor aches and pains due to:
 - headache
 - muscle aches

Questions or comments? Call 1.800.222.1888

Stop use and ask a doctor if:

- any new symptoms occur
- painful area is red or swollen

These could be signs of a serious condition.

When using this product do not exceed recommended dosage.

Directions:

- do not take more than directed (see overdose warning)

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

Warnings:

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

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.

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.

Inactive ingredients:

microcrystalline cellulose, sodium starch glycolate, magnesium stearate, silicon dioxide

Other information:

- store between 20-25°C (68-77°F)
- do not use if neck band is broken or missing
- close cap tightly after use
- read all product information before using. Keep this box for important information.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Uses:

- temporarily relieves minor aches and pains due to:
 - headache
 - muscle aches



Compare to
Excedrin®
Tension Headache
active
ingredients†

NDC 69732-007-01

TENSION HEADACHE RELIEF

Acetaminophen, Caffeine

- Pain Reliever Aid
- Pain Aid

100 CAPLETS
ASPIRIN FREE

TENSION HEADACHE RELIEF

acetaminophen, caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69732-007
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	

Product Characteristics

Color	white	Score	score with uneven pieces
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	HT565
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69732-007-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/09/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	11/09/2020	

Labeler - Hi-Tech Nutraceuticals, LLC (606221443)

Registrant - Hi-Tech Nutraceuticals, LLC (606221443)

Establishment

Name	Address	ID/FEI	Business Operations
Hi-Tech Nutraceuticals, LLC		080787135	pack(69732-007)

Establishment

Name	Address	ID/FEI	Business Operations
Hi-Tech Nutraceuticals, LLC		606221443	manufacture(69732-007)

Revised: 12/2022

Hi-Tech Nutraceuticals, LLC