

EXTRA STRENGTH ACETAMINOPHEN- acetaminophen 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 ingredient (in each caplet)	Purpose
Acetaminophen 500 mg.....	Pain reliever/fever reducer

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:

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are allergic to acetaminophen or any of the inactive ingredients in this product.

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children.
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.

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children.
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.

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Questions or comments? Call 1.800.222.1888

Stop use and ask a doctor if:

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

Directions:

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

Adults and children 12 years and over	<ul style="list-style-type: none">■ take 2 caplets every 6 hours while symptoms last■ do not take more than 6 caplets in 24 hours, unless directed by a doctor■ do not use for more than 10 days unless directed by a doctor
Children under 12 years	ask a doctor

Warnings:

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

- more than 4,000 mg of acetaminophen in 24 hours, which is the daily maximum 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.

Other information:

- store between 20-25°C (68-77°F)
- do not use if printed seal under cap is cut, torn or missing

Inactive ingredients:

hypromellose, magnesium stearate, sodium starch glycolate

Uses:

- temporarily relieves minor aches and pains due to:
 - the common cold
 - headache
 - backache
 - minor pain of arthritis
 - toothache
 - muscular aches
 - premenstrual and menstrual cramps
- temporarily reduces fever

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Compare to
Tylenol®
Extra Strength
active ingredient†

FOR ADULTS

EXTRA STRENGTH

Acetaminophen 500MG

- Pain Reliever
- Fever Reducer

30 CAPLETS

EXTRA STRENGTH ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69732-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

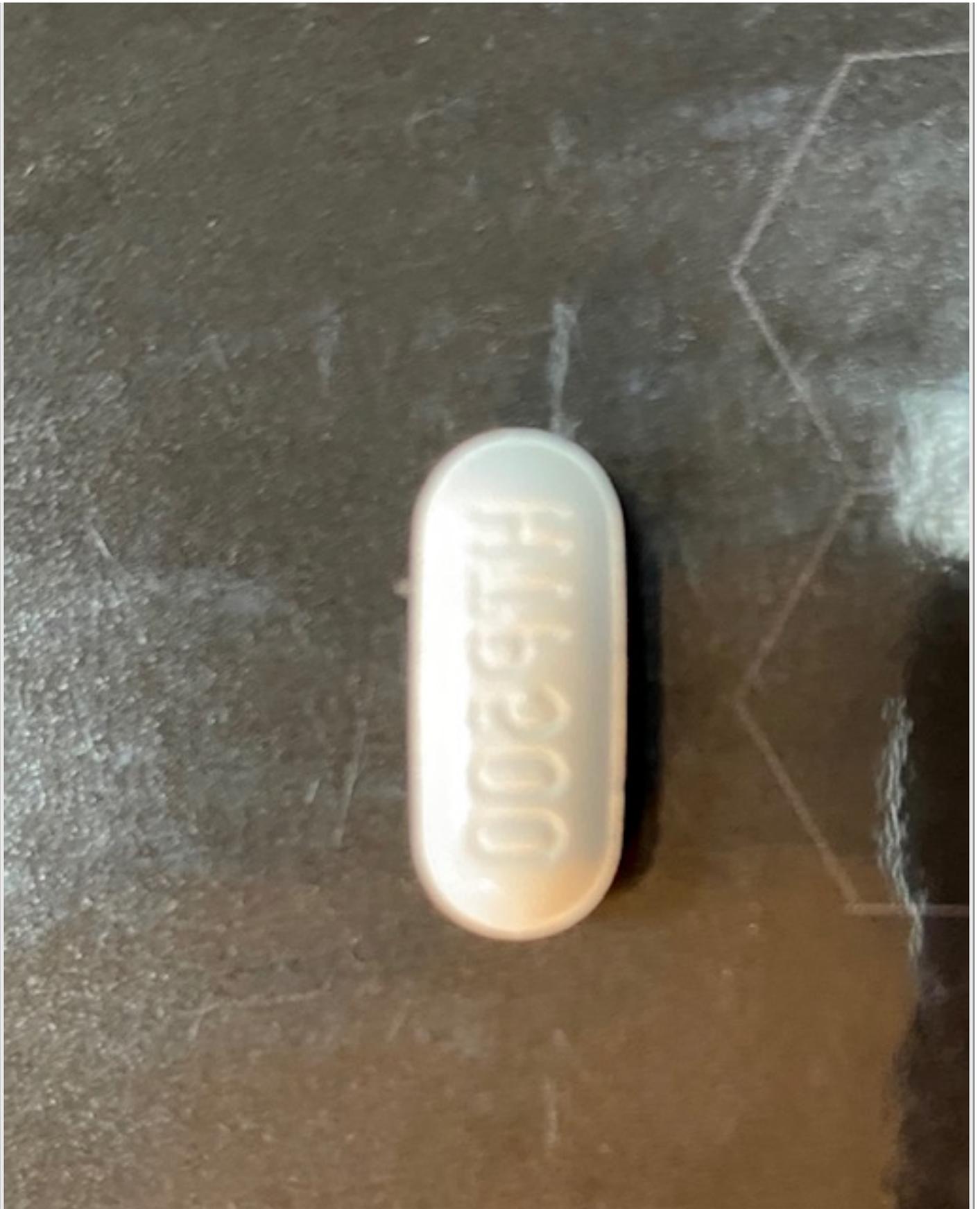
Ingredient Name	Strength
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	white	Score	score with uneven pieces
Shape	CAPSULE	Size	18 mm
Flavor		Imprint Code	HTP500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69732-001-01	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2020	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/30/2020	

Labeler - Hi-Tech Nutraceuticals, LLC (606221443)

Establishment

Name	Address	ID/FEI	Business Operations
Hi-Techn Nutraceutical, LLC		080787135	pack(69732-001)

Establishment

Name	Address	ID/FEI	Business Operations
Hi-Tech Nutraceuticals, LLC		606221443	manufacture(69732-001)

Revised: 4/2020

Hi-Tech Nutraceuticals, LLC