

**EXTRA STRENGTH PAIN AID- acetaminophen, aspirin, caffeine tablet**  
**Hi-Tech Nutaceuticals, 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.*

**Extra Strength Pain Aid**

<b>Active ingredients (in each tablet)</b>	<b>Purpose</b>
Acetaminophen 250 mg.....	Pain Reliever
Aspirin 250 mg (NSAID*).....	Pain Reliever
Caffeine 65 mg.....	Pain Reliever Aid
*nonsteroidal anti-inflammatory drug	

**Ask a doctor before use if:**

- you have liver disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

**Ask a doctor or pharmacist before use if you are taking:**

- a prescription drug for diabetes, gout, or arthritis
- any other drug, or are under a doctor's care for any serious condition

**Do not use:**

- if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer
- 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.** 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.

**If pregnant or breast-feeding,** ask a health care professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

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Caffeine 65 mg.....	Pain Reliever Aid
*nonsteroidal anti-inflammatory drug	

**Questions or comments?** call 1.800.222.1888

**Stop use and ask a doctor if:**

- an allergic reaction occurs. Seek medical help right away.
  - you experience any of the following signs of stomach bleeding:
    - feel faint
    - vomit blood
    - have a bloody or black stools
    - have stomach pain that does not get better
    - ringing in the ears or loss of hearing occurs
    - 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
    - any new symptoms occur.
- These could be signs of a serious condition

When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

### **Warnings:**

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**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.

**Allergy alert:** Aspirin may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock

**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

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you ■ are age 60 or older ■ have had stomach ulcers or bleeding problems ■ take a blood thinning (anticoagulant) or steroid drug ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed

**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 heart beat.

### **Directions:**

■ do not use more than directed ■ drink a full glass of water with each dose  
■ adults and children 12 years of age and over: take 2 tablets every 6 hours; not more than 8 tablets in 24 hours ■ under 12 years: ask a doctor

### **Inactive ingredients:**

microcrystalline cellulose, dicalcium phosphate, sodium starch glycolate, magnesium stearate, stearic acid, silica

### **Other information:**

■ store at 20° - 25°C (68° - 77°F) ■ close cap tightly after use ■ read all product information before using ■ do not use if printed seal under cap is cut, torn or missing

### **Uses:**

■ temporarily relieves minor aches and pains due to:  
■ headache ■ cold ■ arthritis ■ muscular aches  
■ toothache ■ premenstrual & menstrual cramps



Compare to  
**Excedrin<sup>®</sup>**  
Extra Strength  
active  
ingredients†

# EXTRA STRENGTH PAIN AID

*Acetaminophen, Aspirin (NSAID), Caffeine*

- Pain Reliever
- Pain Reliever Aid

## 30 TABLETS

### EXTRA STRENGTH PAIN AID

acetaminophen, aspirin, caffeine tablet

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69732-006
Route of Administration	ORAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CAFFEINE</b> (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: L11K75P92J)	
<b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	score with uneven pieces
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	HT565
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69732-006-01	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-Tech Nutraceuticals, LLC		080787135	pack(69732-006)

## Establishment

Name	Address	ID/FEI	Business Operations
Hi-Tech Nuraceuticals, LLC		606221443	manufacture(69732-006)

Revised: 1/2023

Hi-Tech Nutraceuticals, LLC