

**HEAD AND COLD- acetaminophen, guaifenesin, dextromethorphan hbr,  
phenylephrine hcl 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.*

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**Head and Cold**

<b>Active ingredients (in each caplet)</b>	<b>Purpose</b>
Acetaminophen 325 mg.....	Pain reliever
Guaifenesin 200 mg.....	Expectorant
Dextromethorphan HBr 10 mg.....	Cough suppressant
Phenylephrine HCl 5 mg.....	Nasal decongestant

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**Ask a doctor before use if you have:**

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough that occurs with too much phlegm (mucus)

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

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## Do not use:

- with any other product containing acetaminophen (prescription or nonprescription). if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients.

## Keep out of reach of children.

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

## Active ingredients (in each caplet) Purpose

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## Questions or comments?

Call 1.717.667.2142

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## Stop use and ask a doctor if:

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts

These could be signs of a serious condition

## **When using this product do not exceed recommended dosage**

**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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### ***Warnings:***

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

- more than 12 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

**Sore throat warning:** if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly.

### ***Inactive ingredients:***

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

### ***Uses:***

- minor aches and pains
- nasal congestion
- sinus congestion and pressure
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- headache
- cough
- sore throat

## ***Directions:***

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

Adults and children 12 years and over	<ul style="list-style-type: none"><li>■ take 2 caplets every 4 hours</li><li>■ swallow whole - do not crush, chew or dissolve</li><li>■ do not take more than 12 caplets in 24 hours</li></ul>
Children under 12 years	do not use this adult product in children under 12 years of age, this will provide more than the recommended dose (overdose) and may cause liver damage

## ***Other information:***

- store between 20-25°C (68-77°F)
  - do not use if printed seal under cap is cut, torn, or missing
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Compare to  
Tylenol®  
Cold + Head  
active  
ingredients†

FOR ADULTS

# COLD + HEAD CONGESTION SEVERE

**Acetaminophen,** *Phenylephrine HCl, Guaifenesin*  
*Pain Reliever-Fever Reducer, Nasal Decongestant, Expectorant*

- Headache + Body Aches
- Fever + Sore Throat
- Mucus + Congestion

**30 CAPLETS**

## HEAD AND COLD

acetaminophen, guaifenesin, dextromethorphan hbr, phenylephrine hcl tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69732-003
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH)	DEXTROMETHORPHAN	10 mg

(DEXTROMETHORPHAN - UNII:7355X3ROTS)		HYDROBROMIDE	10 mg	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)		GUAIFENESIN	200 mg	
Inactive Ingredients				
Ingredient Name			Strength	
MAGNESIUM STEARATE (UNII: 70097M6I30)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
Product Characteristics				
Color	white	Score	score with uneven pieces	
Shape	CAPSULE (20)	Size	20mm	
Flavor		Imprint Code	HTP540	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69732-003-01	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 final		part341	04/30/2020	

**Labeler -** Hi-Tech Nutraceuticals, LLC (606221443)

## Establishment

Name	Address	ID/FEI	Business Operations
Hi-Tech Nutraceuticals, LLC		080787135	pack(69732-003)

## Establishment

Name	Address	ID/FEI	Business Operations
Hi-Tech Nutraceuticals, LLC		606221443	manufacture(69732-003)