NIGHTTIME SLEEP AID- acetaminophen, diphenhydramine 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.

Sleep Aid

Active ingredients (in each caplet)	Purpose
Acetaminophen 500 mg	Pain Reliever
Diphenhydramine HCl 25 mg	Nighttime Sleep Aid

Ask a doctor before use if you have:

- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate
- glaucoma

Ask a doctor or pharmacist before use if you are:

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

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.
- with any other product containing diphenhydramine, even one used on skin
- in children under 12 years of age
- 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***
Acetaminophen 500 mg	Pain Reliever
Diphenhydramine HCl 25 mg	Nighttime Sleep Aid

Questions or comments? Call 1.800.222.1888

Stop use and ask a doctor if:

- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

These could be signs of a serious condition.

When using this product:

- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery

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.

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 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

Inactive ingredients:

hypromellose, magnesium stearate, sodium starch glycolate

Uses:

temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness

Other information:

■ **store between 20-25°C (68-77°F)**

■ **do not use if printed seal under cap is cut, torn or missing**

Directions:

do not take more than directed (see overdose warning)

■ adults and children 12 years an over **-** take 2 caplets at bedtime

■ do not take more than 2 caplets of this product in 24 hours

■ children under 12 years do not use

■ Pain Reliever
■ Nighttime Sleep Aid

30 CAPLETS

NIGHTTIME SLEEP AID

acetaminophen, diphenhydramine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69732-005
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	white	**Score**	score with uneven pieces
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	HTP525
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69732-005-01	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(69732-005)

Establishment

Name	Address	ID/FEI	Business Operations
Hi-Tech Nutraceuticals, LLC		606221443	manufacture(69732-005)

Revised: 12/2022 Hi-Tech Nutraceuticals, LLC