NIGHTTIME SEVERE COLD AND COUGH- acetaminophen, diphenhydramine, phenylephrine powder, for solution
RARITAN PHARMACEUTICALS INC

DRx Choice Nighttime Severe Cold & Cough Chamomile & White Tea Flavors 6 Packets

Active ingredients (in each packet)

Acetaminophen 650 mg

Diphenhydramine hydrochloride 25 mg

Phenylephrine hydrochloride 10 mg

Purposes

Pain reliever / fever reducer

Antihistamine / Cough Suppressant

Nasal Decongestant

Uses

- temporarily relieves these symptoms due to a cold:
  - minor aches and pains
  - minor sore throat pain
  - headache
  - nasal and sinus congestion
  - runny nose
  - sneezing
  - itchy nose or throat
  - itchy, watery eyes due to hay fever
  - cough due to minor throat and bronchial irritation
- temporarily reduces fever

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
- 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

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.

Do not use

- in a child under 12 years of age
- if you are allergic to acetaminophen
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or a pharmacist.
- with any other product containing diphenhydramine, even one used on the skin
- if you are now 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 a MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

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

When using this product

- **do not exceed recommended dosage**
- avoid alcoholic drinks
- marked drowsiness may occur
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs

- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- cough comes back or occurs with fever, rash or headache that lasts. There could be signs of a serious condition.

If pregnant or breast- feeding,

ask a health care professional before use.

Keep out of reach of children.

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

Directions

- **do not use more than directed**
- take every 4 hours while symptoms persist, not to exceed 5 packets in 24 hours unless directed by a doctor

Age	Dose
adults and children 12 years of age and over	one packet
children under 12 years of age	do not use

- dissolve contents of one packet into 8 oz. hot water: sip while hot. Consume entire drink within 10 - 15 minutes.
- if using a microwave, add contents of one packet to 8 oz. of cool water: stir briskly before and after heating, Do not overheat.

Other information

- each packet contains: **potassium 6 mg**
- store at room temperature. Protect from excessive heat and moisture.

Inactive ingredients

citric acid, FD& C Yellow No. 6, flavors, maltodextrin, potassium chloride, silica, sucralose, sucrose,

Questions or comments?

1- **866-467-2748**

Principal Display Panels

Compare to the active ingredients in Theraflu ®Nighttime Severe Cold & Cough

NDC# 68163-541-06

Nighttime

Severe Cold & Cough

ACETAMINOPHEN

PAIN RELIEVER/FEVER REDUER

DIPHENHYDRAMINE HCl

ANTIHISTAMINE/ COUGH SUPPRESSANT

PHENYLEPHRINE HCl

NASAL DECONGESTANT

- Aspartame free
- Sodium Free

Relieves:

Body Ache & Fever

- Cough
- Fever
- Headache
- Nasal Congestion
- Runny Nose
- Sneezing
- Sore Throat Pain

6 PACKETS

Honey Lemon Flavor

Infused with Chamomile & White Tea Flavors

TAMPER EVIDENT: DO NOT USE IF INNER SEALED PACKET IS TORN

Manufactured by:

Raritan Pharmaceuticals

8 Joanna Court

East Brunswick, NJ 08816

*This product is not manufactured or distributed by GSK consumer Healthcare, owner of the registered trademark THERAFLU ®Nighttime Severe Cold & Cough.

Display

NIGHTTIME SEVERE COLD AND COUGH

acetaminophen, diphenhydramine, phenylephrine powder, for solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68163-541
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	HONEY, LEMON	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68163-541-06	6 in 1 CARTON	03/22/2019	
1		1 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/22/2019	

Labeler - RARITAN PHARMACEUTICALS INC (127602287)

Revised: 9/2025 RARITAN PHARMACEUTICALS INC