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

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.

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 final	part341	03/22/2019	

Labeler - RARITAN PHARMACEUTICALS INC (127602287)

Revised: 7/2022 RARITAN PHARMACEUTICALS INC