SEVERE COLD AND COUGH DAYTIME- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride 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 Daytime Severe Cold and Cough Drug Facts

Active ingredients (in each packet)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Phenylephrine HCl 10 mg

Purposes

Pain reliever/fever reducer

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
- 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 pharmacist.
- 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 an 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
- trouble urinating due to an enlarged prostate gland
- 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 the blood thinning drug warfarin

When using this product

- do not exceed recommended dosage

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 rash or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (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. Do not take more than 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 product from heat and moisture.

Inactive ingredients

citric acid, FD& C Blue No. 1, FD&C Red No. 40, flavor, maltodextrin, potassium chloride, silica, sucralose, sucrose.

Questions or comments?

1-866-467-2748

Package/Label Principal Display Panel

NDC# 68163-540-06

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

Day Time

Severe Cold & Cough

Acetaminophen

Pain Reliever/Fever Reducer

Dextromethorphan HBr

Cough Suppressant

Phenylephrine HCl

Nasal Decongestant

- Aspartame free
- Sodium free

Relieves

- Body Ache
- Cough
- Fever
- Headache
- Nasal Congestion
- Sore Throat Pain

6 PACKETS

BERRY FLAVOR

Infused With Menthol & Green Tea Flavor

TAMPER EVIDENT: DO NOT USE INNER SEALED PACKET IF TORN

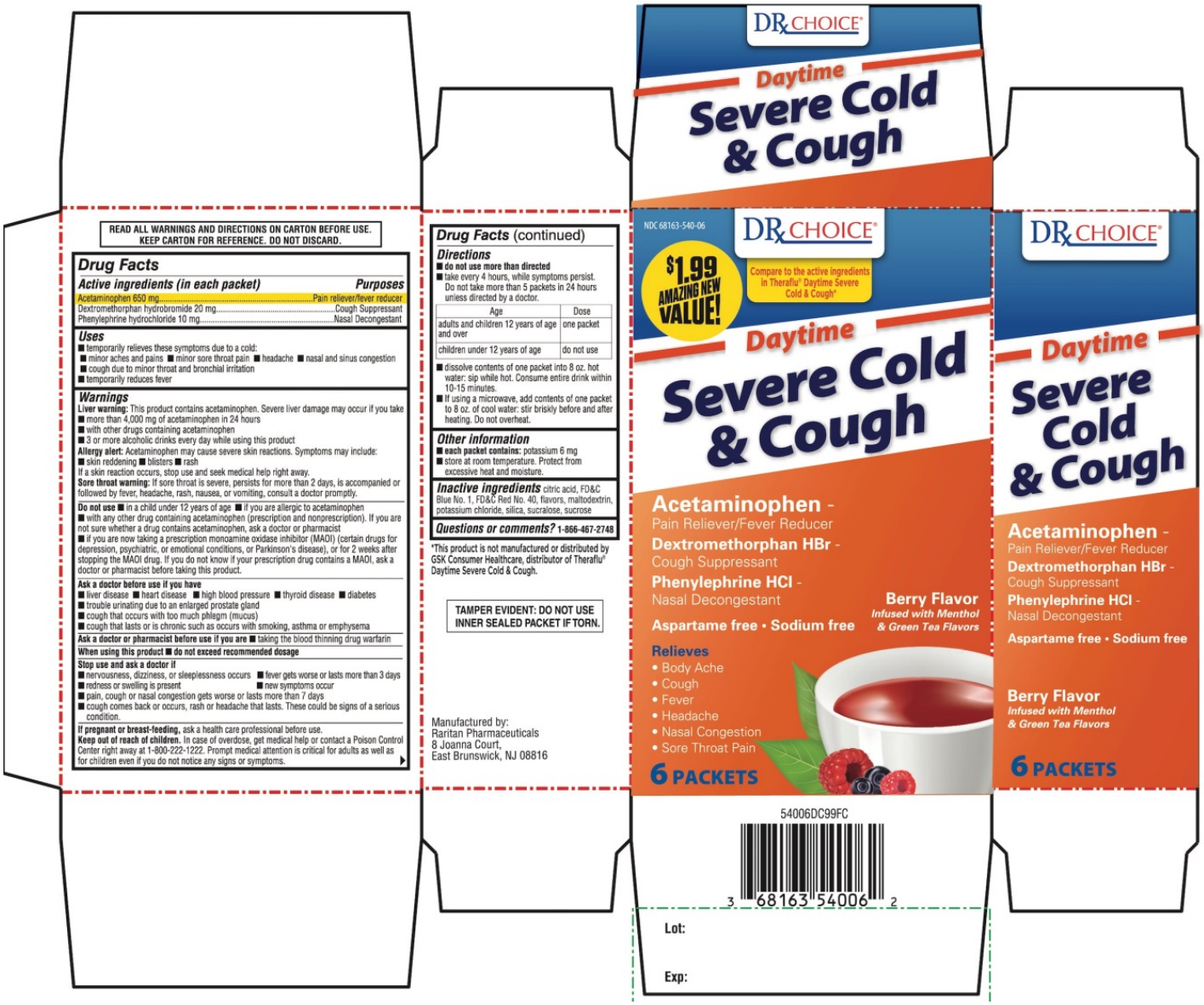
Manufactured by:

Raritan Pharmaceuticals

8 Joanna Court,

East Brunswick, NJ 08816

This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Theraflu® Daytime Severe Cold & Cough.



SEVERE COLD AND COUGH DAYTIME

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68163-540
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	WHITE (mixture of white to light to dark red particles) , RED	**Score**	
Shape		**Size**	
Flavor	BERRY, MENTHOL	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68163-540-06	6 in 1 CARTON; Type 0: Not a Combination Product	03/14/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/14/2019	

Labeler - RARITAN PHARMACEUTICALS INC (127602287)

Revised: 9/2023 RARITAN PHARMACEUTICALS INC