

**DRX CHOICE CHILDRENS STUFFY NOSE AND CHEST CONGESTION- guaifenesin and phenylephrine hcl solution
RARITAN PHARMACEUTICALS**

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 Children's Stuffy Nose & Chest Congestion

Drug Facts

Active ingredients (in each 5 mL)

Guaifenesin, USP 100 mg

Phenylephrine HCl, USP 2.5 mg

Purposes

Expectorant

Nasal Decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
 - nasal congestion due to a cold
 - stuffy nose

Warnings

Do not use in a child who is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if the child has

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- cough that occurs with too much phlegm (mucus)

- persistent or chronic cough such as occurs with asthma

When using this product

do not use more than directed

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur
- symptoms do not get better within 7 days or occur with fever
- cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache.

These could be signs of a serious illness.

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.

Directions

- do not give more than 6 doses in any 24 hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor

Age	Dose
Children 6 years to under 12 years	10 mL every 4 hours
Children 4 years to under 6 years	5 mL every 4 hours
Children under 4 years	do not use

Other information

- **each 5 mL contains:** sodium 3 mg
- very low sodium
- store at room temperature
- do not refrigerate
- dosing cup provided

Inactive ingredients

anhydrous citric acid, edetate disodium, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sorbitol solution, sucralose, xanthan gum.

Questions or Comments?

1-866-467-2748

Package Label-Principal Display Panel 4 FL OZ (118 mL Bottle)

*Compare to the active ingredients in Children's Mucinex® Stuffy Nose & Chest Congestion

NDC 68163-748-04

DRx Choice®

Children's

Stuffy Nose & Chest Congestion

Guaifenesin (Expectorant)

Phenylephrine HCl (Nasal Decongestant)

Relieves: Stuffy Nose, Chest congestion, Breaks Up Mucus

Dosage Cup Included

Mixed Berry Flavor

Naturally & artificially flavored

For Ages 4 & Over

4 FL OZ (118 mL)

TAMPER-EVIDENT: DO NOT USE IF PRINTED INNER SEAL UNDER CAP IS TORN OR MISSING

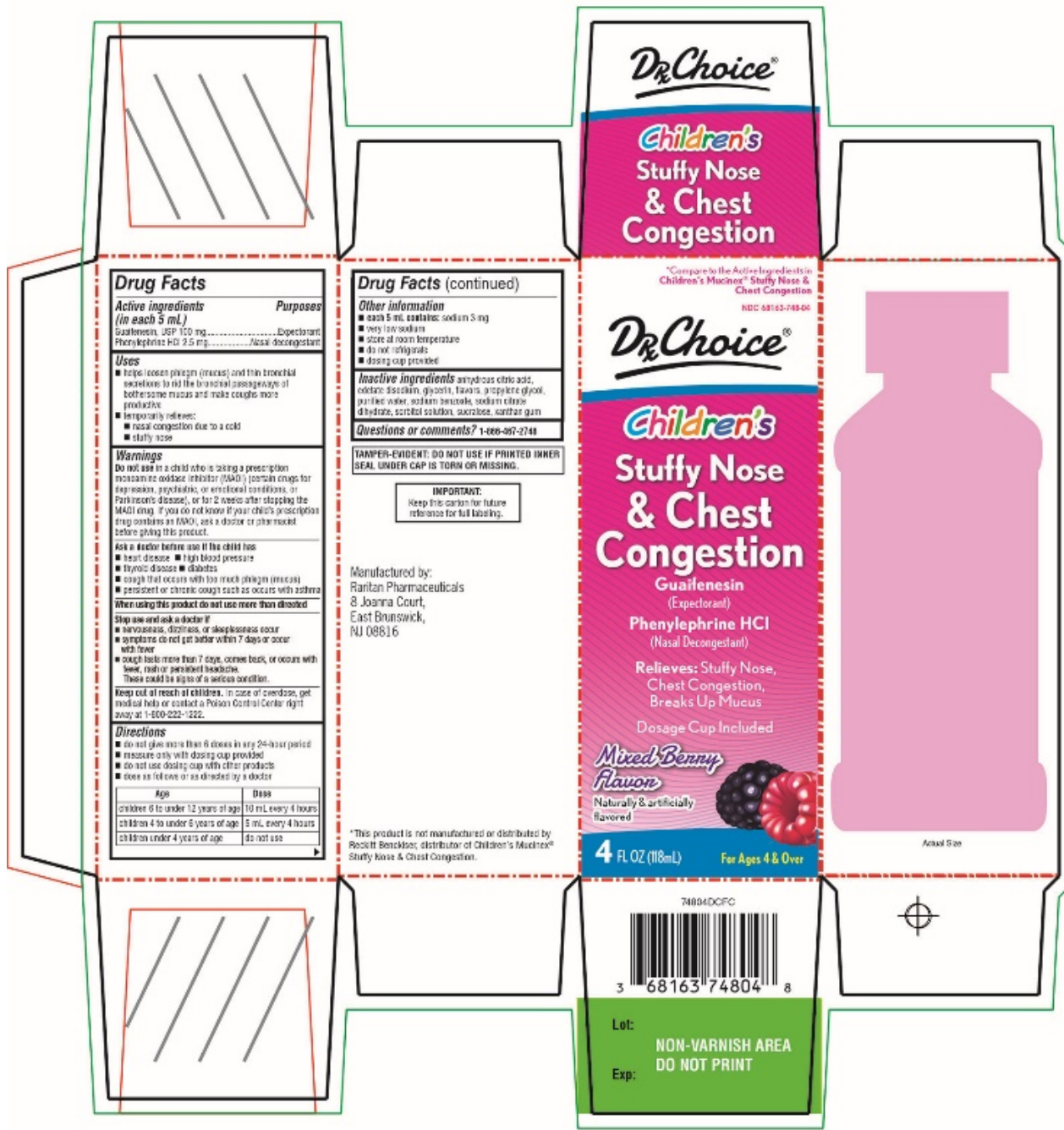
IMPORTANT: Keep this carton for future reference on full labeling.

Manufactured by:

Raritan Pharmaceuticals

8 Joanna Court. East Brunswick

NJ 08816



DRX CHOICE CHILDRENS STUFFY NOSE AND CHEST CONGESTION

guaifenesin and phenylephrine hcl solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68163-748
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL
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Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	PINK	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68163-748-04	1 in 1 CARTON	04/24/2023	
1		118 mL in 1 BOTTLE; 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	04/24/2023	

Labeler - RARITAN PHARMACEUTICALS (127602287)

Revised: 5/2023

RARITAN PHARMACEUTICALS