# WALGREENS- childrens stuffy nose and cold solution WALGREENS CO.

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.

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## Walgreens Children's Stuffy Nose and Cold

#### **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. Avoid foods or beverages that contain caffeine.

#### 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

- your child gets nervous, dizzy or sleepless
- 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
- mL= milliliter

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, sorbitol solution, sucralose, xanthan gum.

#### **Questions or Comments?**

1-866-467-2748

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

#### Walgreens

Compare to Children's Mucinex® Stuffy Nose & Cold active ingredients††

NDC 0363-7480-04

#### Children's Dye-Free Stuffy Nose & Cold

# GUAIFENESIN, USP 100 mg/EXPECTORANT PHENYLEPHRINE HCl, USP 2.5 mg/

NASAL DECONGESTANT

DYE FREE

ALCOHOL FREE

- Relief from stuffy nose & chest congestion
- Breaks up mucus

#### **4 YEARS & OLDER**

Mixed Berry Flavor
NATURALLY AND ARTIFICIALLY FLAVORED
4 FL OZ (118 mL)
DOSAGE CUP PROVIDED

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.

DISTRIBUTED BY: WALGREEN CO.

200 WILMOT RD., DEERFIELD, IL 60015

Walgreens

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#### WALGREENS

childrens stuffy nose and cold solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-7480
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	
<b>PHENYLEPHRINE HYDRO CHLO RIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
EDETATE DISO DIUM (UNII: 7FLD91C86K)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SO DIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)		
SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics			
Color	PINK (Pink to Red)	Score	
Shape		Size	
Flavor	BERRY, MANGO, PINEAPPLE	Imprint Code	
Contains			

l	Packaging			
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
l	1 NDC:0363-7480-04	1 in 1 CARTON	05/15/2019	
ı	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	05/15/2019	

# Labeler - WALGREENS CO. (008965063)

Revised: 7/2019 WALGREENS CO.