

CHILDRENS MUCINEX COUGH - guaifenesin and dextromethorphan hydrobromide solution
Physicians Total Care, 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.

**Children's
Mucinex[®]
Cough**

Drug Facts

<i>Active ingredients (in each 5 mL)</i>	<i>Purpose</i>
Dextromethorphan HBr 5 mg	Cough suppressant
Guaifenesin 100 mg	Expectorant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
 - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
 - the intensity of coughing
 - the impulse to cough to help your child get to sleep

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

- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with asthma

Stop use and ask a doctor if 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.

Directions

- do not take 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	5 mL – 10 mL every 4 hours

children 4 years to under 6 years	2.5 mL – 5 mL every 4 hours
children under 4 years	do not use

Other information

- each 5 mL contains: **sodium 3 mg**
- tamper evident: do not use if neckband on bottle cap is broken or missing
- store between 15-30°C (59-86°F)
- do not refrigerate
- dosing cup provided

Inactive ingredients

citric acid anhydrous, dextrose, D&C red #33, FD&C red #40, flavors, glycerin, methylparaben, potassium sorbate, propylene glycol, propylparaben, purified water, saccharin sodium, sodium hydroxide, sucralose, xanthan gum

Questions?

1-866-MUCINEX (1-866-682-4639) You may also report side effects to this phone number.

Dist. by: Reckitt Benckiser Inc.

Parsippany, NJ 07054-0224

Relabeling of "Additional Barcode Label" by:

Physicians Total Care, Inc.

Tulsa, OK 74146

PRINCIPAL DISPLAY PANEL - 188 mL Bottle Carton

Children's
Mucinex®

Cough

Expectorant

Cough Suppressant

Guaifenesin 100 mg

Dextromethorphan HBr 5 mg

Cough

Chest Congestion

Breaks up Mucus

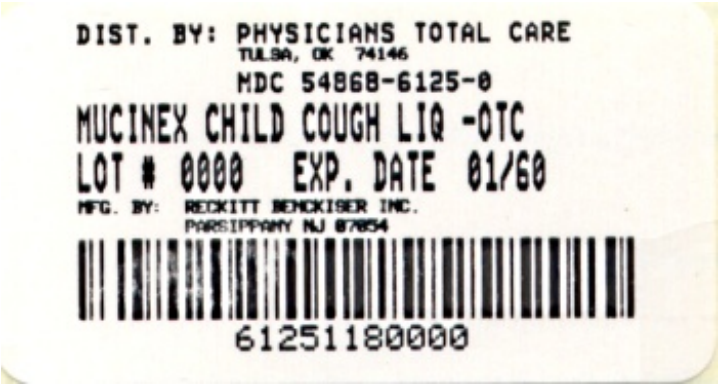
Cherry

Flavor Liquid

4 FL OZ

(118 mL)

NDC 54868-6125-0



CHILDRENS MUCINEX COUGH

guaifenesin and dextromethorphan hydrobromide solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-6125(NDC:63824-274)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name		Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)		100 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)		5 mg in 5 mL

Inactive Ingredients	
Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
DEXTROSE (UNII: IY9XDZ35W2)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	pink	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:548 68-6 125-0	1 in 1 CARTON		
1		118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/19/2010	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel