CHILDRENS MUCUS RELIEF CHEST CONGESTION PLUS COUGH- dextromethorphan hydrobromide, guaifenes in solution CVS Pharmacy

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 Mucus Relief Chest Congestion Plus Cough

Drug Facts

Active Ingredients (in each 5 mL)

Dextromethorphan HBr, USP, 5mg Guaifenesin, USP, 100 mg

Purpose

Cough Suppressant

Expectorant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold.
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive.

Warnings

Do not use

if your child is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for two 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 your child has

- cough that occurs with too much phlegm (mucus).
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema.

Stop use and ask a doctor if

cough lasts for more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.

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 a 24 hour period.
- give the recommended number of vials below, following the instructions under How to Open and

Use on the side panel.

• empty all liquid in each Single-Use Vial when dosing.

Dosing Chart

Age	Dose (mL)
under 4 years	Do not use
4-6 years	1 Single-Use Vial (5mL) Every 4 hours
6-12 years	1-2 Single-Use Vial (5mL Each) Every 4 hours

Inactive Ingredients

Citric Acid, Glycerin, Mixed Berry Flavor, Propylene Glycol, Purified Water, Sodium Benzoate, Sodium Saccharine, Sorbitol, Sucralose, Trisodium Citrate Dihydrate, Xanthan Gum.

Other Information

- each Single-Use Vial contains 8mg of sodium.
- store at 20-25 °C (68-77 °F).
- tamper evident: do not use if top flap of carton is open. Do not use if any vials are open or broken.

Questions or Comments?

1-800-719-9260

Package Labeling:



CHILDRENS MUCUS RELIEF CHEST CONGESTION PLUS COUGH

dextromethorphan hydrobromide, guaifenesin solution

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:69842-260 Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL	

Inactive Ingredients		
Ingredient Name	Strength	
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)		

GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TRISO DIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
XANTHAN GUM (UNII: TTV12P4NEE)	

ı	Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:69842-260-01	1 in 1 BOX	12/04/2018		
	1	100 mL in 1 VIAL; 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	12/04/2018		

Labeler - CVS Pharmacy (062312574)

Revised: 10/2019 CVS Pharmacy