

DR. SIMI CHILDREN S COUGH- dextromethorphan hbr, guaifenesin syrup
Farmacias De Similares TX LLC

Drug Facts

Active ingredients (in each 5 mL)

Dextromethorphan HBr 5 mg

Guaifenesin 100 mg

Purposes

Dextromethorphan HBr 5 mg	Cough suppressant
Guaifenesin 100 mg	Expectorant

Uses

- temporarily relieves cough as may occur with the common cold
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus.

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

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

Stop use and ask a doctor if

- cough persists for more than 1 week, tends to recur, or is accompanied by a 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 accidental 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
- shake well before use
- measure only with dosing cup provided
- keep dosing cup with product
- 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
- store at room temperature 15-30°C (59-86°F)
- Do not refrigerate
- TAMPER-EVIDENT FEATURE: Do not use if printed safety seal is torn, broken or missing.

Inactive ingredients

citric acid, FD&C blue #1, FD&C red #40, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum.

Questions or comments?

855-280-1079

Principal Display Pane

NDC: 85786-604-04

DR. SIMI

Children's Cough

Dextromethorphan HBr 5 mg

Cough Suppressant

Guaifenesin 100 mg

Expectorant

Ages 4+ Years

- Controls cough
- Relieves chest congestion
- Breaks up mucus

Free of alcohol, parabens & high fructose corn syrup

4 fl oz (118 mL)

Cherry Flavor

Compare to the active ingredients in Children's Mucinex® Cough*

*This product is not manufactured or distributed by RB Health (USA), distributor of Children's Mucinex® Cough.

Distributed by:

FARMACIAS DE SIMILARES TX LLC.

800 Brazos St Ste 260, Austin, TX, 78701, USA

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www.drsimi.com

Carton labeling



DR. SIMI CHILDREN S COUGH

dextromethorphan hbr, guaifenesin syrup

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:85786-604

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
CITRIC ACID (UNII: 2968PHW8QP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85786-604-04	1 in 1 CARTON	05/08/2026	
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 Drug	M012	05/08/2026	

Labeler - Farmacias De Similares TX LLC (119489934)

Establishment

Name	Address	ID/FEI	Business Operations
Rnv LLC		118917568	label(85786-604) , manufacture(85786-604) , pack(85786-604)

Revised: 5/2026

Farmacias De Similares TX LLC