

**SANATOS MUCUS RELIEF COLD TODDLERS- dextromethorphan hbr,
guaifenesin liquid
Pharmadel LLC**

Santos Toddler Mucus (AP/ PLE)

Drug Facts

Active Ingredients & Purposes

Active ingredients (in each 2.5 mL)

Dextromethorphan HBr 2.5 mg

Guaifenesin 50 mg.....

Purposes

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 drain the bronchial tubes

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 a

- cough that is accompanied by excessive 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 the child has a

cough that persists for more than 7 days, tends to recur, 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.

Directions

- do not give a child more than **6 doses** in 24 hour period
- repeat the dose every 4 hours
- use only included oral syringe to measure dose

Age

children 2 to under 6 years of age
children under 2 years of age

Dose

2.5 mL every 4 hours
consult a doctor

Other information

- store between 68-77°F (20-25°C)
- do not refrigerate
- keep carton for full direction for use

Inactive ingredients

anhydrous citric acid, D&C red #33, FD&C red #40, flavor, glycerin, propylene glycol, sodium benzoate, sorbitol solution, sucralose, xanthan gum, water

Questions?

+1-866-359-3478 (M-F) 9 AM to 5 PM EST or www.pharmadel.com

Distributed by / Distribuido por:

PHARMADEL LLC

New Castle, DE 19720

Principal Display Panel



SANATOS MUCUS RELIEF COLD TODDLERS

dextromethorphan hbr, guaifenesin liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55758-307

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	50 mg in 2.5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	2.5 mg in 2.5 mL

Inactive Ingredients

Ingredient Name	Strength
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-307-02	59 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	10/17/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/17/2017	

Labeler - Pharmadel LLC (030129680)