

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

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.

Santos Toddler Mucus Relief Cough (Apta)

Drug Facts

Active Ingredients & Purposes

Active ingredients (in each 2.5 mL)	Purposes
Dextromethorphan HBr 2.5 mg	Cough suppressant
Guaifenesin 50 mg.....	Expectorant

Use

- 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

- cough that is accompanied by excessive phlegm (mucus) or
- 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 persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. These could be signs 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 any 24-hour period
- repeat the dose every 4 hours
- measure with the dosing device provided
- do not use any other dosing device
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Age	Dose
Children 2 to under 6 years of age	2.5 mL every 4 hours
Children under 2 years of age	ask a doctor

Other information

- each dose (2.5 mL) contains: sodium 1.5 mg
- store between 20-25°C (68-77°F)
- oral dosing device included
- do not refrigerate
- Keep carton for full direction for use

Inactive ingredients

anhydrous citric acid, D&C red #33, dextrose monohydrate, FD&C red #40, flavors, glycerin, maltitol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sucralose, xanthan gum

Questions or comments?

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

Principal Display Panel

Sanatos

Toddlers

Mucus Relief

Cough

Dextromethorphan HBr.....Cough Suppressant

Guaifenesin.....Expectorant

FOR CHILDREN 2 TO UNDER 6 YEARS

Cherry Flavor

2 FL OZ (59 mL)

- ALCOHOL FREE
- NON-DROWSY

Includes Syringe



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		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
		50 mg

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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTITOL (UNII: D65DG142WK)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
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 final	part341	10/17/2017	

Labeler - Pharmadel LLC (030129680)