

**SANATOS CHILDRENS MUCUS RELIEF COUGH- dextromethorphan
hydrobromide and guaifenesin liquid
Pharmadel LLC**

SanaTos Children's Mucus Relief Cough (DEACTIVATED)

Drug Facts

Active Ingredients (in each 5 mL teaspoonful)	Purpose
Dextromethorphan HBr, USP 5 mg	Cough Suppressant
Guaifenesin, USP 100 mg	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

- cough that occurs with too much 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

- cough lasts more than 7 days, comes back or occurs with 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 Poison Control Center right away.

Directions

- do not take more than 6 doses in any 24-hour period

Age	Dose
Children 6 years to under 12 years	1-2 teaspoonful s (tsps) every 4 hours
Children 4 years to under 6 years	½-1 teaspoonful (tsp) every 4 hours
Children under 4 years	do not use

Other information

- each teaspoon contains: sodium 3 mg
- store between 20-25 C (68-77 F)
- do not refrigerate
- dosage cup provided
- Keep cartoon for full directions for use

Inactive ingredients

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

Questions?

Call weekdays from 9:30 AM to 4:30 PM EST 1-877-798-5944

Distributed by

PHARMDL®

Seaford, DE 19973

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton

NDC # 55758-007-04

SanaTos®

Children's

Mucus Relief

COUGH

Cherry Flavor

Dextromethorphan HBr

Cough Suppressant

Guafenesin

Expectorant

Relieves Chest Congestion

Thins & Loosens Mucus

Alcohol-Free
For Ages 4 to 12

4 FL OZ (118 mL)

NDC#55758-007-04

SanaTos®

Children's



Mucus Relief COUGH

Cherry Flavor

Dextromethorphan HBr.....Cough Suppressant
Guaifenesin.....Expectorant

Relieves Chest Congestion
Thins & Loosens Mucus



Alcohol-Free
For Ages 4 to 12

DO NOT USE IF PRINTED SEAL
UNDER CAP IS TORN OR MISSING

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Children

SanaTos

NDC#55758-007-04

SanaTos

Niños



Drug Facts (continued)

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• Alivio de la tos por irritación menor de la garganta y bronquios. Ayuda a aflojar la flema y secreciones para drenar los tubos bronquiales.

• No usar en niño que esté tomando algún medicamento recetado para la depresión, condiciones psiquiátrico emocional o enfermedad de Parkinson. Si usted no sabe si el medicamento recetado de su niño contiene MAOI consulte con su médico o Farmacéutico antes de darle el producto.


Descongestion Nasal

TOS

Sabor a Cereza

Dextrometorfano HBr.....Supresor de tos
Guafenesina.....Expectorante

Alivia la Congestión de Pecho
Expectorante de Flemas




Libre-de-Alcohol
Para Edades 4 a 12

4 FL OZ (118 mL)

• no tome mas de 6 dosis en periodo de 24 horas.

AGE/EDAD	DOSE/DOSIS
Niños de 6 a de 12 años	1 a 2 cucharaditas cada 4 horas
Niños de 4 años a menores de 6 años	1/2 - 1 cucharaditas cada 4 horas
Niños menores de 4 años	no usar

Distributed by/Distribuido por:
PHARMADEL®
Seaford, DE 19973
www.pharmadelusa.com
1-866-359-3478



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SANATOS CHILDRENS MUCUS RELIEF COUGH

dextromethorphan hydrobromide and guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55758-007
Route of Administration	ORAL		

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
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)				
MALTITOL (UNII: D65DG142WK)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
XANTHAN GUM (UNII: TTV12P4NEE)				
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:55758-007-04	1 in 1 CARTON	10/10/2013	01/01/2026
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		10/10/2013	01/01/2026

Labeler - Pharmadel LLC (030129680)