

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

SanaTos Children's Mucus Relief Cough

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 carton 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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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.

**Descongestión 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



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	
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 final	part341	10/10/2013	

Labeler - Pharmadel LLC (030129680)

Revised: 9/2023

Pharmadel LLC