

**SANATOS CHILDREN COUGH AND CONGESTION CHERRY- dextromethorphan hbr 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.*

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**SanaTos Children Cough & Congestion Cherry (APTA)**

**Drug Facts**

**Active Ingredients & Purposes**

<b>Active Ingredients (in each 5 mL teaspoonful)</b>	<b>Purposes</b>
Dextromethorphan HBr 5 mg	Cough Suppressant
Guaifenesin 100 mg	Expectorant

**Uses**

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a common 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.

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**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

**Stop use and ask a doctor, if the child has a**

- cough lasts more than 7 days, tends to come back, or 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 Poison Control Center right away.

**Directions**

- do not give a child more than 6 doses in any 24-hour period

<b>Age</b>	<b>Dose</b>
Children 6 to under 12 years of age	1-2 teaspoonfuls (tsps) every 4 hours
Children 2 to under 6 years of age	½-1 teaspoonful (tsp) every 4 hours
Children under 2 years of age	consult a doctor

**Other information**

- sodium: 3 mg per teaspoonful
- store at 20- 25° C (68- 77° F)
- do not refrigerate
- dosage cup included

**TAMPER EVIDENT:** DO NOT USE IF PRINTED SEAL UNDER CAP IS TORN OR MISSING.

**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?**

**1-866-359-3478** (M-F) 9 AM to 5 PM EST or [www.pharmadel.com](http://www.pharmadel.com)

**Distributed by:**

**PHARMDL LLC**  
Georgetown, DE 19702

**Principal Display Panel**

SanaTos®

Children

Cough & Chest Congestion

Cherry Flavor

COUGH SUPPRESSANT • EXPECTORANT

Dextromethorphan HBr • Guaifenesin

Helps Loosen Chest Congestion

- ALCOHOL FREE
- NON-DROWSY

For Ages 2 to 12

4 FL OZ (118 mL)



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**PHARMADEL LLC**  
Georgetown, DE 19702



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

**NO UTILICE SI EL SELLO IMPRESO DEBAJO DE LA TAPA ESTA ROTO O FALTA.**

**Datos Farmacológicos**

Ingredientes activos	Propósitos
(in cada cucharadita, 5mL) Dextrometorfano HBr 5 mg	Supresor de la tos
Guaifenesina 100 mg	Expectorante

**Usos**  
■ alivia temporalmente la tos producida por una leve irritación bronquial como puede ocurrir con el resfriado común ■ ayuda a aliviar la flemas (mucoosidad) y las secreciones bronquiales para el drenaje de los tubos bronquiales

**Advertencias**  
No utilice ■ en niños que están tomando un inhibidor de la monoamino oxidasa prescripción (MAOI) (ciertos medicamentos para la depresión, trastornos psiquiátricos o emocionales, o la enfermedad de Parkinson), o durante 2 semanas después de dejar de tomar el MAOI. Si usted no sabe si el medicamento recetado a su niño contiene un MAOI, consulta un médico o farmacéutico antes de darle este producto.

Pregúntele a un médico antes de usar si su niño tiene una ■ tos que persiste o se acompaña de fiebre excesiva (mucoosidad) ■ tos persistente o crónica como ocurre con el asma

Para el uso y consulta a un médico si su niño tiene ■ una tos que persiste por más de 7 días, tiende a repetirse, o se acompaña de fiebre, erupción cutánea o dolor de cabeza persistente. Estos podrían ser signos de una condición grave.

**MANTENGA FUERA DEL ALCANCE DE LOS NIÑOS.** En caso de sobredosis accidental, busque ayuda médica o contacte un Centro de Control de Intoxicación inmediatamente.

**Instrucciones** ■ no le dé a un niño más de 6 dosis en cualquier período de 24 horas

Edad	Dosis
niños de 6 a menos de 12 años de edad	1-2 cucharaditas (cdas) cada 4 horas
niños de 2 a menos de 6 años de edad	½ -1 cucharadita (cda) cada 4 horas
niños menos de 2 años de edad	consulta con un médico

**Otra información**  
■ **sodio:** 3 mg por cucharadita ■ conserve a 20-25°C (68-77°F)  
■ no refrigerar ■ taza de dosificación incluida

**Inactive ingredients**  
Ácido cítrico anhidro, D&C rojo # 33, dextrosa monohidrato, FD&C rojo #40, sabores, glicerina, maltitol, propilenglicol, agua purificada, sacarina de sodio, benzoato de sodio, sucralosa, goma de xantano.

**Preguntas?** 1-866-359-3478 (L-V) 9AM a 5PM Este o [www.pharmadel.com](http://www.pharmadel.com)

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BX-036 Rev 02



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# SANATOS CHILDREN COUGH AND CONGESTION CHERRY

dextromethorphan hbr and guaifenesin liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55758-013
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>DEXTROSE MONOHYDRATE</b> (UNII: LX22YL083G)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MALTITOL</b> (UNII: D65DG142WK)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Product Characteristics

<b>Color</b>	red	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-013-04	1 in 1 BOX	01/01/2016	
1		118 mL in 1 BOTTLE, WITH APPLICATOR; 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	01/01/2016	

**Labeler** - Pharmadel LLC (030129680)

Revised: 9/2023

Pharmadel LLC