

**TUKOL CHILDREN COUGH AND CONGESTION- dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride syrup**  
**Genomma Lab USA**

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**Tukol® Children's Cough & Congestion Syrup**

***Drug Facts***

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**Active Ingredient (in each 5 mL or 1 teaspoon)**

Dextromethorphan HBr, 5 mg  
Guaifenesin, 50 mg  
Phenylephrine HCl, 2.5 mg

**Purpose**

Cough Suppressant  
Expectorant  
Nasal Decongestant

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**Uses**

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes
- temporarily relieves these symptoms occurring with a cold:
  - nasal congestion
  - cough due to minor throat and bronchial irritation

**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 taking this product.

**Ask a doctor before use if the child has**

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough that occurs with too much phlegm (mucus)

**Ask a doctor or pharmacist before use if the child is** taking any other oral nasal decongestant or stimulant.

**Do not exceed recommended dosage.**

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occurs
- symptoms do not get better within 7 days or are accompanied by fever
- cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or

persistant 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 (1-800-222-1222) right away.

### Directions

- Do not take more than 6 doses in any 24 hour period
- measure only with dosing cup provided
- keep dosing cup with product
- TSP = teaspoon

age	dose
children 6 to under 12 years	2 teaspoons (10 mL) every 4 hours
children 4 to under 6 years	1 teaspoon (5 mL) every 4 hours
children under 4 years	do not use

### Other information

- **each teaspoon (5 mL) contains:** sodium 3 mg
- store at 15-30°C (59-86°F). Do not refrigerate.

### Inactive ingredients

citric acid, FD&C blue #1, FD&C red #40, flavor, glyverin, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

### Questions or comments?

**1-877-994-3666**

Distributed by:  
Genomma Lab USA Inc.,  
Houston, TX 77098

**PRINCIPAL DISPLAY PANEL - 118 ml Bottle Carton**

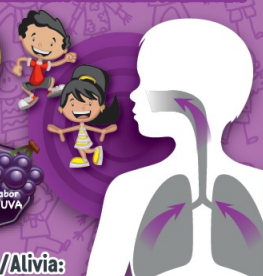
# Tukol<sup>®</sup>

## CHILDREN'S NIÑOS

### COUGH & CONGESTION TOS Y CONGESTIÓN

Dextromethorphan HBr / Guaifenesin / Phenylephrine HCl  
Dextrometorfano HBr / Guaifenesina / Fenilefrina HCl

Ages  
Edades  
4+



flavor/sabor  
GRAPE/UVA

**Relieves/Alivia:**

- COUGH / TOS
- NASAL CONGESTION / CONGESTIÓN NASAL
- CHEST CONGESTION / CONGESTIÓN DE PECHO

4 FL OZ (118 ml)

**Drug Facts**

**Active ingredients Purposes**  
(in each 5 mL, 1 teaspoon)

Dextromethorphan HBr, 5 mg.....Cough Suppressant  
Guaifenesin, 50 mg.....Expectorant  
Phenylephrine HCl, 2.5 mg.....Nasal Decongestant

**Uses**

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes
- temporarily relieves these symptoms occurring with a cold:
  - nasal congestion
  - cough due to minor throat and bronchial irritation

**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 taking this product.

**Ask a doctor before use if the child has**

- heart disease
- diabetes
- high blood pressure
- thyroid disease
- cough that lasts or is chronic such as occurs with asthma
- cough that occurs with too much phlegm (mucus)

**Ask a doctor or pharmacist before use if the child is** taking any other oral nasal decongestant or stimulant.

**Do not exceed recommended dosage.**

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occurs
- symptoms do not get better within 7 days or are accompanied by fever
- cough lasts more than 7 days, comes back, 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 (1-800-222-1222) immediately.

**Drug Facts (continued)**

**Directions**

- do not take more than 6 doses in any 24 hour period
- measure only with dosing cup provided
- keep dosing cup with product • TSP = teaspoon

age	dose
children 6 to under 12 years	2 teaspoons (10 mL) every 4 hours
children 4 to under 6 years	1 teaspoon (5 mL) every 4 hours
children under 4 years	do not use

**Other information**

- each teaspoon (5 mL) contains: sodium 3 mg
- store at 15-30°C (59-86°F). Do not refrigerate.

**Inactive ingredients** citric acid, FD&C blue #1, FD&C red #40, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

**Questions or comments?** 1-877-994-3666

**Información del Medicamento (continuación)**

**Consulte a su médico si el niño padece**

- insuficiencia cardíaca • hipertensión arterial
- diabetes • enfermedad tiroidea
- tos duradera o crónica, tal como ocurre con el asma
- tos que se produce con mucha flema (mucosidad)

**Consulte a su médico o farmacéutico antes de utilizarlo si el niño está tomando cualquier otro descongestionante o estimulante nasal oral.**

**No exceder la dosis recomendada.**

**Suspenda su uso y consulte a su médico si**

- presenta nerviosismo, mareos o insomnio
- los síntomas no mejoran dentro de 7 días o están acompañados de fiebre
- la tos dura más de 7 días, vuelve, o está acompañada de fiebre, dolor de cabeza persistente o erupción cutánea. Estos podrían ser signos de una condición grave.

**Manténgase fuera del alcance de los niños.** En caso de sobredosis, solicite ayuda médica o póngase en contacto inmediatamente con un Centro de Control Envenenamiento (1-800-222-1222).

**Instrucciones**

- no exceder 6 dosis en un periodo de 24 horas
- medir solo con la copa dosificadora incluida
- mantenga la copa dosificadora con este producto
- TSP = cucharadita

edad	dosis
niños 6 a menores de 12 años	2 cucharaditas (10 mL) cada 4 horas
niños 4 a menores de 6 años	1 cucharadita (5 mL) cada 4 horas
niños menores de 4 años	no usar


**Información adicional**

- cada cucharadita (5 mL) contiene: sodio 3 mg
- almacenar entre 15-30 °C (59-86 °F). No refrigerar.

**Ingredientes inactivos** ácido cítrico, FD&C azul #1, FD&C rojo #40, sabor, glicerina, propilenglicol, agua purificada, benzoato de sodio, sorbitol, sucralosa, goma de xantano

**¿Preguntas o comentarios?** 1-877-994-3666

Distributed by / Distribuido por:  
Genomma Lab USA Inc.,  
Houston, TX 77098



Tukol<sup>®</sup>  
 Children's  
 COUGH & CONGESTION  
 Dextromethorphan HBr / Guaifenesin / Phenylephrine HCl  
 Ages  
 4+  
 Relieves:  
 • COUGH  
 • NASAL CONGESTION  
 • CHEST CONGESTION  
 4 FL OZ (118 ml)

## TUKOL CHILDREN COUGH AND CONGESTION

dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride syrup

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50066-308
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Dextromethorphan Hydrobromide</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	5 mg in 5 mL
<b>Guaifenesin</b> (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	50 mg in 5 mL
<b>Phenylephrine Hydrochloride</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	2.5 mg in 5 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

**Product Characteristics**

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-308-04	1 in 1 CARTON	06/01/2022	
1		118 mL in 1 BOTTLE, PLASTIC; 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	06/01/2022	

**Labeler** - Genomma Lab USA (832323534)**Registrant** - Genomma Lab USA (832323534)

