

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

Tukol[®] Children's Cough & Congestion Syrup

Drug Facts

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

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) immediately.

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

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

PRINCIPAL DISPLAY PANEL - 118 ml Bottle Carton

Tukol[®]

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

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(in each 5 mL, 1 teaspoon)

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Guaifenesin, 50 mg.....Expectorant
Phenylephrine HCl, 2.5 mg.....Nasal Decongestant

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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

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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

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Houston, TX 77098



Tukol[®]
 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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-308
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	50 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

Inactive Ingredients

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

Product Characteristics

Color	purple	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

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)

