

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

Tukol® Cough & Congestion Syrup

Drug Facts

Active Ingredient (in each 5 mL or 1 teaspoon)	Purpose
Dextromethorphan HBr, 10 mg	Cough Suppressant
Guaifenesin, 100 mg	Expectorant
Phenylephrine HCl, 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 if you are now 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 prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema

Ask a doctor or pharmacist before use if you are taking any other oral nasal decongestant or stimulant.

Do not exceed recommended dosage.

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- 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.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- Do not take more than 6 doses in any 24 hour period
- This adult strength product is not intended for use in children under 12 years of age
- measure only with dosing cup provided
- keep dosing cup with product
- TSP = teaspoon

age	dose
adults and children 12 years and over	2 teaspoons (10 ml) every 4 hours
children under 12 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

anhydrous citric acid, FD&C red #40, flavor, glycerin, menthol, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose

Questions or comments?

1-877-994-3666 Monday to Friday from 8 am to 6 pm, Central Time.

Distributed by:
Genomma Lab USA Inc.,
Houston, TX 77027

PRINCIPAL DISPLAY PANEL - 118 ml Bottle Carton

Tukol[®]

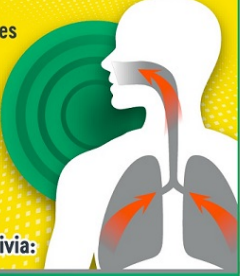
MULTI-SYMP TOM
MULTI-SÍNTOMA

COUGH & CONGESTION

TOS Y CONGESTIÓN

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

Ages/Edades
12+



Relieves/Alivia:

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

4 FL OZ (118 ml)

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Drug Facts (continued)

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Información del Medicamento (continuación)

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

No exceda la dosis recomendada.

Suspenda su uso y consulte a su médico si
■ se siente nervioso, mareado o con insomnio
■ los síntomas no mejoran en los siguientes 7 días o se acompañan de fiebre
■ la tos persiste por más de 7 días, regresa, o se presenta acompañada por fiebre, erupción o dolor de cabeza persistente. Estos podrían ser signos de una condición grave.

En caso de embarazo o lactancia, consulte a un profesional médico antes de su uso.
Manténgase fuera del alcance de los niños. En caso de sobredosis, obtenga ayuda médica o contacte al Centro de Control de Envenenamiento de manera inmediata.

Indicaciones
■ no tomar más de 6 dosis en un período de 24 horas
■ este producto de concentración para adultos no está previsto para su uso en niños menores de 12 años de edad
■ medir solo con la copa dosificadora incluida
■ mantenga la copa dosificadora con este producto
■ TSP = cucharadita


edad	dosis
adultos y niños 12 años de edad y mayores	2 cucharaditas (10 mL) cada 4 horas
niños menores de 12 años	no utilizar

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

Ingredientes inactivos
ácido cítrico anhidro, FD&C rojo #40, sabor, glicerina, mentol, propilenglicol, agua purificada, benzoato sódico, solución de sorbitol, sucralosa

¿Preguntas o comentarios?
1-877-994-3666 Lunes a Viernes de 8 am a 6 pm, Tiempo del Centro.

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



Tukol[®]

MULTI-SYMP TOM

COUGH & CONGESTION

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Ages
12+

Relieves:

- COUGH
- NASAL CONGESTION
- CHEST CONGESTION

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-510
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	2 mg in 1 mL
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	20 mg in 1 mL
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-510-04	1 in 1 CARTON	06/07/2020	
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	06/07/2020	

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

