**TUKOL MULTI SYMPTOM COLD - dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid**
**Genomma Lab USA, Inc.**

*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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**Active ingredients**

**DRUG FACTS**

**Active ingredients**
**(in each 5 mL tsp)**
Dextromethorphan HBr, USP 10 mg
Guaifenesin, USP 100 mg
Phenylephrine HCL, USP 5 mg

**Purposes**

Cough Suppressant
Expectorant
Nasal Decongestant

**Keep out of reach of children**

**Keep out of reach of children.**

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

**Uses**

- help 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 Ask a doctor or pharmacist before use**

**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.

**When using this product do not use more than directed.**

**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.

**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

Age - adults and children 12 years and over  Dose - 2 teaspoons every 4 hours

Age - children under 12  Dose - do not use

**Other information**
- each teaspoon contains: sodium 3 mg
- store at 20□25 ° C (68□77 ° F). Do not refrigerate.
- dosage cup provided

**Inactive ingredients**

anhydrous citric acid, FD and C red no. 40, glycerin, menthol, natural and artificial flavor, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose

**Questions or comments?**

1 877 99 GENOM (43666)

**Product Label Tukol 504 DPL**

**Tukol®**

**DO NOT USE IF PRINTED SEAL UNDER CAP**

**IS TORN OR MISSING**

**Dextromethorphan HBr / Guaifenesin / Phenylephrine HCL**

**Expectorant/Cough Suppressant/Nasal Decongestant**

**Tukol®**

**Cough & Congestion**

- Quiets Cough
- Thins and loosens phlegm
- Clears Nasal Congestion

Ages/ 12+ ***4 FL OZ (118 mL)***

2000005853

6 50066 00012 6

LOT No.
Exp.

Distributed by
Genomma Lab USA Inc.

Houston, TX 77027

BX-006 Rev. 03

Genoma Lab.®

COATING FREE AREA

COATING FREE AREA

## Drug Facts (continued)

### Other information
- each teaspoon contains: **sodium 3 mg**
- store at 20–25°C (68–77°F). Do not refrigerate.
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Anhydrous citric acid, FD&C Red # 40, glycerin, menthol, natural & artificial flavor, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose

### Questions or comments?
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## Información del Medicamento

### Ingredientes activos
**(en cada cucharadita de 5 ml) Propósito**

Dextrometorfano HBr, 10 mg _____ Antitusivo
Guaifenesina, 100 mg _____ Expectorante
Fenilefrina HCl, 5 mg _____ Descongestionante Nasal

### Usos
- ayuda a desprender las flemas (mucosidad) y a adelgazar las secreciones bronquiales para drenar los tubos bronquiales
- alivia temporalmente los siguientes síntomas que se presentan con el resfriado:
  - congestión nasal
  - tos debida a irritación menor de garganta y bronquios

### Advertencias
**No utilizarlo** si usted está tomando un inhibidor de la monoamino oxidasa (IMAO) de prescripción (ciertos medicamentos para la depresión, condiciones siquiátricas o emocionales, o enfermedad de Parkinson), o durante 2 semanas después de suspender el medicamento IMAO. Si usted desconoce si su medicamento de prescripción contiene un IMAO, consulte a su médico o farmacéutico antes de tomar este producto.

**Consulte a su médico** si usted padece
- enfermedad cardiaca
- hipertensión
- enfermedad de la tiroides
- diabetes
- problemas al orinar debido a dilatación de la glándula prostática
- tos que se presenta con exceso de flema (mucosidad)
- tos persistente o crónica tal como ocurre con el tabaquismo, asma, bronquitis crónica o enfisema

## Información del Medicamento (continuación)

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

**Cuando use este producto no utilice más de lo indicado**

**Suspenda su uso y consulte a su médico** si
- se siente nervioso, mareado o insomne
- si 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.

| edad | dosis |
|---|---|
| adultos y niños de 12 años y mayores | 2 cucharaditas cada 4 horas |
| niños menores de 12 años | no utilizar |

### Información adicional
- cada cucharadita contiene: **sodio 3 mg**
- almacenar entre 20–25 °C (68–77 °F). No refrigerar.
- incluye vaso dosificador

### Ingredientes Inactivos
Ácido cítrico anhidro, FD&C Rojo # 40, glicerina, mentol, sabor natural & artificial, propilenglicol, agua purificada, benzoato sódico, solución de sorbitol, sucralosa

### ¿Preguntas o comentarios?
**1 877 99 GENOM (43666)**

Distributed by / Distribuido por:
Genomma Lab USA Inc.,
Houston, TX, 77027
BX-006 Rev. 03

Genomma Lab.®

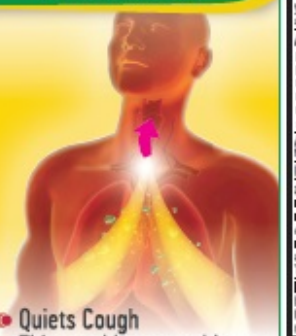
DO NOT USE IF PRINTED SEAL UNDER CAP IS TORN OR MISSING
NO SE USE SI EL SELLO IMPRESO DEBAJO DE LA TAPA ESTA ROTO O FALTA

# Tukol®

Dextromethorphan HBr / Guaifenesin / Phenylephrine HCl
Cough Suppressant / Expectorant / Nasal Decongestant
Dextrometorfano / Guaifenesina / Fenilefrina HCl
Antitusivo / Expectorante / Descongestivo Nasal

# Tukol®

## COUGH & CONGESTION
## TOS Y CONGESTIÓN



- Quiets Cough
- Thins and loosens phlegm
- Clears Nasal Congestion

- Calma la tos
- Reduce y afloja las flemas
- Despeja la congestion nasal

Ages / Edades **12+** **4 FL OZ (118 ml)**

2000005853

50066 00012 6

LOT No. / LOTE.
Exp. / Exp.

COATING FREE AREA

## Drug Facts

### Active ingredients (in each 5 mL tsp) — Purpose
Dextromethorphan HBr, 10 mg _____ Cough Suppressant
Guaifenesin, 100 mg _____ Expectorant
Phenylephrine HCl, 5 mg _____ Nasal Decongestant

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- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes
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- heart disease
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- 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**
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- 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
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| age | dose |
|---|---|
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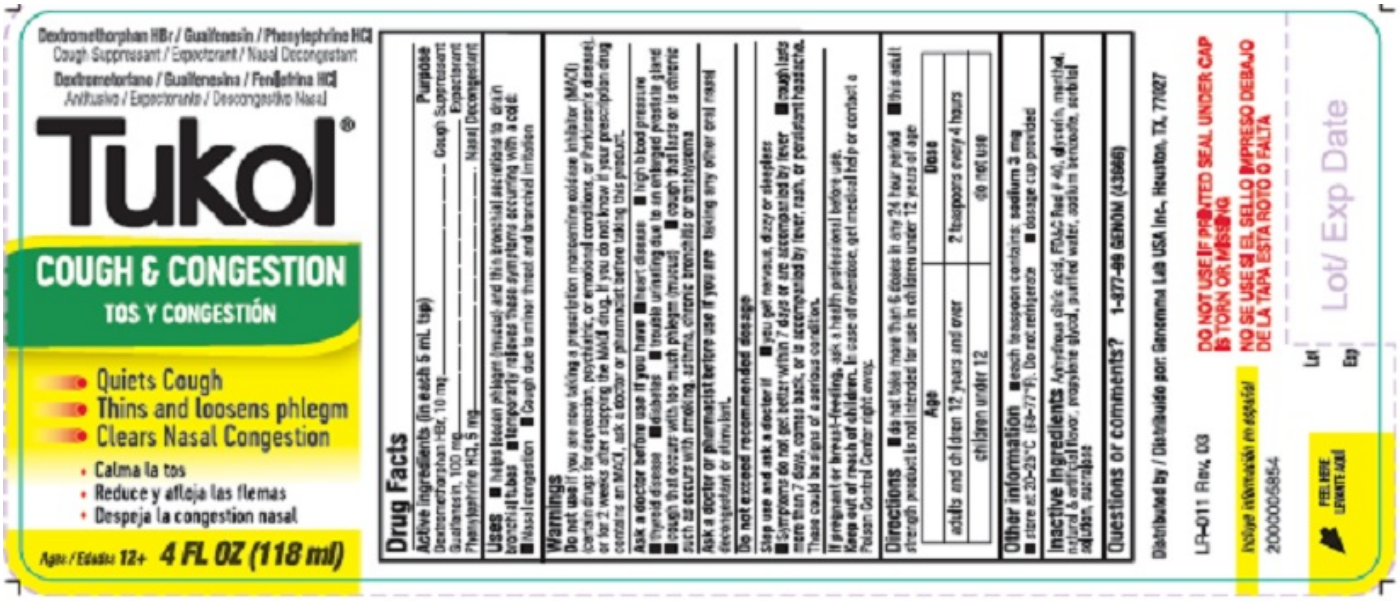


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# TUKOL MULTI SYMPTOM COLD

dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:50066-504 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg in 5 mL |
| **GUAIFENESIN** (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 100 mg in 5 mL |
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg in 5 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** (UNII: 506T60A25R) | |
| **SUCRALOSE** (UNII: 96K6UQ3ZD4) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| 1 | NDC:50066-504-24 | 118 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/15/2012 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part341 | 05/15/2012 | |

## Labeler - Genomma Lab USA, Inc. (832323534)

## Registrant - AptaPharma Inc. (790523323)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| AptaPharma Inc. | | 790523323 | manufacture(50066-504) |

Revised: 8/2019 Genomma Lab USA, Inc.