

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

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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)**

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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

# Tukol®

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

### Drug Facts (continued)

#### Other information

- each teaspoon contains sodium 5 mg
- store at 20-25°C (68-77°F). Do not refrigerate.
- dosage cup provided

#### Inactive ingredients

Arhydrous citric acid, FD&C Red # 40, glycerin, menthol, natural & artificial flavor, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucrose

#### 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 \_\_\_\_\_ Descongestión Nasal

#### Usos

- ayuda a disminuir las flemas (mucoidad) 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 utilice si usted está tomando un inhibidor de la monoaminoxidasa (MAO) de prescripción (ciertos medicamentos para la depresión, condiciones psiquiátricas o emocionales, o enfermedad de Parkinson), o durante 2 semanas después de suspender el medicamento MAO. Si usted desconoce si su medicamento de prescripción contiene un MAO, consulte a su médico o farmacéutico antes de tomar este producto.

#### Consulte a su médico si usted padece

- enfermedad cardíaca
- hipertensión
- enfermedad de la tiroides
- diabetes
- problemas al orinar debidos a distensión de la glándula prostática
- tos que se presenta con exceso de flema (mucoidad)
- 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 inestable
  - si los síntomas no mejoran en los siguientes 7 días o se acompañan de fiebre
  - si los síntomas persisten por más de 7 días, regresan, o se presentan acompañados por fiebre, erupción o dolor de cabeza persistentes. Estos podrían ser signos de una infección 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 el Centro de Control de Envenenamiento de manera inmediata.

#### Indicaciones

- no tomar más de 6 dosis en un periodo 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 5 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, azúcar

#### ¿Preguntas o comentarios?

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



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 alfoja las flemas
- Despeja la congestión nasal

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

### 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

#### 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 sluggish
- 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

age	dose
adults and children 12 years and over	2 teaspoons every 4 hours
children under 12	do not use

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LOT No. / LOTE,  
Exp. / Exp.

COATING FREE AREA

Dextromethorphan HBr / Guaifenesin / Phenylephrine HCl  
Cough Suppressant / Expectorant / Nasal Decongestant  
Dextrometorfan / Guafenesina / Fenilefrina HCl  
Antitusivo / Expectorante / Descongestivo Nasal

# Tukol

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- Calma la tos
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- Despeja la congestión nasal

Age / Edad: **T2+** **4 FL OZ (118 ml)**

**Drug Facts**

**Active ingredients (in each 5 mL tip):** Dextromethorphan HBr, 10 mg; Guaifenesin, 100 mg; Phenylephrine HCl, 5 mg

**Purpose:** Cough Suppressant; Expectorant; Nasal Decongestant

**Uses:** Helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchi (if tubes); Temporarily relieves these symptoms occurring with a cold; Nasal congestion; Cough due to either 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 extreme 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, 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.

Age	Dose
adults and children 12 years and over	2 teaspoons every 4 hours
children under 12	see label

**Other information:** Each teaspoon contains sodium 3 mg; store at 20-25°C (68-77°F); Do not refrigerate; dosage cap provided

**Inactive ingredients:** Anhydrous citric acid, FD&C Red # 40, dextro, menthyl, natural & artificial flavor, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

**Questions or comments?** 1-877-96 GENOM (43666)

Distributed by / Distribuido por: Genentech Lab USA Inc., Houston, TX, 77027  
LP-011 Rev. 03  
NDC: 50066-504  
2000006864

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

Lot: \_\_\_\_\_ Exp. Date: \_\_\_\_\_  
FELIPE URBINA-JOE

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## TUKOL MULTI SYMPTOM COLD

dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50066-504
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<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)	

## 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 Drug	M012	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: 12/2024

Genomma Lab USA, Inc.