

**TUKOL X-PECTO MIEL 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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**Tukol® X-PECTO MIEL Cough & Cold 533**

**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.**

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 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.

**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

**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 yellow # 6, flavor, glycerin, honey, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum

**Questions or comments?**

**1 877 99 GENOM (43666)**

Monday to Friday from 8 am to 6 pm, Central time.

**Tukol X-PECTO MIEL Cough & Cold product label**

**Tukol®**

**X-PECTO MIEL**

**DO NOT USE IF PRINTED SEAL UNDER CAP IS TORN OR MISSING**

Dextromethorphan HBr / Guafenesin / Phenylephrine HCL

Cough Suppressant / Expectorant / Nasal Decongestant

**Tukol®**

**X-PECTO MIEL**

## **Cough & Cold**

- Quiets Cough
- Thins & loosens Phlegm
- Clears Nasal Congestion

**NATURAL HONEY FLAFOR**  
*Ages / 12+ 4 FL OZ (118 ml)*

2000006935

6 50066 00042 0

LOT no.

Exp.

Distributed by Genomma Lab USA Inc.

Houston TX, 77027

BX-035 Rev. 02

*Genomma Lab.*<sup>®</sup>



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

# Tukol

## X-PECTO HONEY

### COUGH & COLD

#### TOS Y RESFRIADO

- Quiets Cough
- Thins & loosens Phlegm
- Clears Nasal Congestion
- Calms the tuss
- Reduce and afoja las flemas
- Despeja la congestión nasal

NATURAL HONEY FLAVOR / SABOR MIEL NATURAL

Age / Edad 12+ 4 FL OZ (118 ml)

**Drug Facts**

**Active ingredients (in each 5 mL tsp)**  
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, 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

**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&C Yellow # 6, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum

**Questions or comments? 1-877-89 GENOM (436666)**  
Monday to Friday from 8 am to 6 pm, Central time.

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

LR-061 Rev. 02  
Incluye información en español  
20000069336

PEEL HERE  
LEVANTE AQUÍ

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

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**Drug Facts (continued)**

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**Información del Medicamento (continuación)**

**Ingredientes activos (en cada cucharadita de 5 ml)** Propósito  
Dextrometorfan HBr, 10 mg.....Antitusivo  
Guafenesina, 100 mg.....Expectorante  
Fenilefrina HCl, 5 mg.....Descongestivo nasal

**Usos**  
■ ayuda a disminuir 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 debido a irritación menor de garganta y bronquios

**Advertencias**  
No utilice si usted está tomando un inhibidor de la monoamina oxidasa (IMAO) de prescripción (ciertos medicamentos para la depresión, condiciones alquímicas e 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 padeciera**  
■ enfermedad cardíaca ■ alta tensión  
■ enfermedad de la tiroides ■ diabetes  
■ problemas al orinar debido a obstrucción de la glándula prostática  
■ tos que se presenta con exceso de flemas (mucosidad) ■ tos persistente o crónica tal como ocurre con el tabaquismo, asma, bronquitis crónica o emfisema

No exceder la dosis recomendada.

**Información del Medicamento (continuación)**

Consulte a su médico o farmacéutico antes de usarlo si usted está tomando cualquier otro descongestivo nasal o estimulante.

**Suspense su uso y consulte a su médico si**  
■ se siente nervioso, mareado o fatigado  
■ si los síntomas no mejoran en los siguientes 7 días o se acompañan de fiebre  
■ si los peores por más de 7 días, regresan, o se presenta acompañado por fiebre, erupción o dolor de cabeza persistente. Estos pueden 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 y contacte al Centro de Control de Inveniente de manera inmediata.

**Indicaciones**  
■ no tomar más de 6 dosis en un periodo de 24 horas  
■ esta producto de concentración para niños no está diseñado 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 amarillo #6, sabor, glicerina, miel, propilenglicol, agua purificada, benzoato de sodio, solución de sorbitol, sucralosa, goma xantana.

**¿Preguntas o comentarios?**  
1-877-89 GENOM (436666)  
Lunes a Viernes, de 8 am a 6 pm Tiempo del centro.

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

EX-035 Rev. 02 Genomma Lab.®

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Reduce y afoja las flemas  
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dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50066-533
<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	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 YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HONEY</b> (UNII: Y9HIV576FH)	
<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>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	HONEY (HONEY)	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-533-24	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/15/2013	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/15/2013	

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

**Registrant** - AptaPharma Inc. (790523323)

**Establishment**

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(50066-533)

Revised: 8/2019

Genomma Lab USA, Inc.