

TUKOL A- 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.

Active ingredients

DRUG FACTS

Active ingredients

(in each 5 mL, 1 teaspoon)

Dextromethorphan HBr, USP 5 mg

Guaifenesin, USP 50 mg

Phenylephrine HCL, USP 2.5 mg

Purpose

Cough Suppressant

Expectorant

Nasal Decongestant

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 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
- 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.

When using this product

- do not use more than directed

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- symptoms do not get better within 7 days or are accompanied by a 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

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

| age | dose |
|------------------------|-----------------------------|
| children 6 to 12 years | 2 tsp (10 mL) every 4 hours |
| children 4 to 6 years | 1 tsp (5 mL) every 4 hours |
| children under 4 years | do not use |

- do not exceed 6 doses in a 24-hour period
- use enclosed dosage cup
- tsp = teaspoon, mL = milliliter

Other information

- each 5 mL contains: sodium 3 mg
- store at room temperature

Inactive ingredients

citric acid, FD and C Blue # 1, FD and C Red # 40, flavor, glycerin, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

Questions or comments?

1 877 99 GENOM (43666)

Children's Tukul Bottle Label

Children's **Tukul**[®]

Cough Suppressant/Expectorant/Nasal Decongestant
Dextromethorphan HBr | Guaifenesin | Phenylephrine HCl

Ages 4+

Cough and Cold

Gets rid of phlegm

Quiets Cough
Clears nasal congestion

Grape Flavor

4 FL OZ (118 ml)

Drug Facts

| Active ingredients <i>(in each 5 mL, 1 teaspoon)</i> | Purpose |
|--|--------------------|
| Dextromethorphan HBr, 5 mg | Cough suppressant |
| Guaifenesin, 50 mg. | Expectorant |
| Phenylephrine HCl, 2.5 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 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 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
- 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.

When using this product

- do not use more than directed

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 last more than 7 days, comes back, or is accompanied by fever, rash or persistent headache.
- These could be signs of a serious condition.

Drug Facts (continued)

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 exceed 6 doses in a 24-hour period
- use enclosed dosage cup
- tsp = teaspoon, mL = milliliter

| age | dose |
|------------------------|-----------------------------------|
| children 6 to 12 years | 2 teaspoons (10 mL) every 4 hours |
| children 4 to 6 years | 1 teaspoons (5 mL) every 4 hours |

children under 4 years do not use

Other information

- each 5 mL contains: **sodium 3 mg**
- store at room temperature

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? 1-877-99 GENOM (43666)

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

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

LR-063 Rev. 2

PEEL HERE

Children's Tukul Niños
Dextromethorphan HBr | Guaifenesin | Phenylephrine HCl
Dextrometorfano | Guaifenesina | Fenilefrina HCl

Cough & Cold
Tos y Resfriado
Gets rid of phlegm
Quiets Cough
Clears nasal congestion
Elimina la flema
Calm the cough
Despeja la congestión nasal

Ages 4+
Edades 4+

GRAPE FLAVOR | SABOR UVA

4 FL OZ (118 ml)

Drug Facts

Active ingredients (in each 5 mL, 1 teaspoon)

| | |
|----------------------------|--------------------|
| Dextromethorphan HBr, 5 mg | Cough suppressant |
| Guaifenesin, 50 mg | Expectorant |
| Phenylephrine HCl, 2.5 mg | Nasal decongestant |

Purpose

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

Drug Facts (continued)

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.

Directions

- do not exceed 6 doses in a 24-hour period
- use enclosed dosage: cup • tsp = teaspoon, mL = milliliter

| age | dose |
|------------------------|-----------------------------------|
| children 6 to 12 years | 2 teaspoons (10 mL) every 4 hours |
| children 4 to 6 years | 1 teaspoon (5 mL) every 4 hours |
| children under 4 years | do not use |

Other information
• each 5 mL contains sodium 3 mg • store at room temperature

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? 1-877-99 GENOM (43666)

Distributed by / Distribuido por: Genomma Lab USA Inc., Houston, TX 77027
TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING / EVIDENCIA DE MANIPULACIÓN: NO USAR SI EL IMPRESO DE SEGURIDAD DEBajo LA TAPA ESTÁ ROTO O FALTA

LR-063 Rev. 02
PEEL HERE LEVANTE AQUÍ

Children's Tukul Box Label

Children's Tukul®

Cough Suppressant/Expectorant/Nasal Decongestant
Dextromethorphan HBr | Guaifenesin | Phenylephrine HCl

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

Children's Tukul®

Cough Suppressant/Expectorant/Nasal Decongestant
Dextromethorphan HBr | Guaifenesin | Phenylephrine HCl

Ages 4+

Cough and Cold

Gets rid of phlegm

Quiets Cough
Clears nasal congestion

Grape Flavor

4 FL OZ (118 ml)

LOT No.

Exp.

Drug Facts

| Active ingredients (in each 5 mL, 1 teaspoon) | Purpose |
|--|--------------------|
| Dextromethorphan HBr, 5 mg | Cough suppressant |
| Guaifenesin, 50 mg. | Expectorant |
| Phenylephrine HCl, 2.5 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 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 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
- 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.

When using this product

- **do not use more than directed**

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 last 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.

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

8/17

Drug Facts (continued)

Directions

- do not exceed 6 doses in a 24-hour period
- use enclosed dosage cup
- tsp = teaspoon, mL = milliliter

| age | dose |
|------------------------|-----------------------------------|
| children 6 to 12 years | 2 teaspoons (10 mL) every 4 hours |
| children 4 to 6 years | 1 teaspoon (5 mL) every 4 hours |
| children under 4 years | do not use |

Other information

- each 5 mL contains: **sodium 3 mg**
- store at room temperature

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? 1-877-99 GENOM (43666)

BX-037 Rev. 02

2FTAP1MUEWW1B

Children's® Tukol Niños

Cough Suppressant/Expectorant/Nasal Decongestant
Dextromethorphan HBr 1 Guaifenesin 1 Phenylephrine HCl
Antitusivo/Expectorante/Descongestionante Nasal
Dextrometorfano HBr 1 Guaifenesina 1 Fenilefrina HCl

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

Children's® Tukol Niños

Cough Suppressant/Expectorant/Nasal Decongestant
Dextromethorphan HBr 1 Guaifenesin 1 Phenylephrine HCl
Antitusivo/Expectorante/Descongestionante Nasal
Dextrometorfano HBr 1 Guaifenesina 1 Fenilefrina HCl



LOT No. / LOTE.
Exp. / Exp.

Información del medicamento (continuación)

Advertencias

- los duradera o crónica, tal como ocurre con el asma
- los que se produce con mucha flema (mucosidad)

Preguntar a un médico o farmacéutico antes de usar si el niño está tomando algún otro descongestionante o estimulante oral o nasal.

Cuando use este producto

- No use más de lo indicado
- 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 de Envenamamiento (1-800-222-1222).

Instrucciones

- no exceder 6 dosis en un período de 24 horas
- use la tacita dosificadora incluida
- cda = cucharadita, mL = mililitro

| edad | dosis |
|-------------------------|-------------------------------------|
| niños de 6 a 12 años | 2 cucharaditas (10 ml) cada 4 horas |
| niños de 4 a 6 años | 1 cucharaditas (5 ml) cada 4 horas |
| niños menores de 4 años | no usar |

Información adicional

- cada 5 mL contienen: sodio 3 mg
- almacenar a temperatura ambiente

Ingredientes inactivos ácido cítrico, FD & C Azul # 1, FD & C Rojo # 40, saborizante, glicerina, propilenglicol, agua purificada, benzoato de sodio, sorbitol, sacarosa, goma de xantano

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

BX-037 Rev. 02

2TAP1MJCW110

Drug Facts

Active ingredients Purpose

(in each 5 mL, 1 teaspoon)
Dextromethorphan HBr, 5 mg.....Cough suppressant
Guaifenesin, 50 mg.....Expectorant
Phenylephrine HCl, 2.5 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 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
- 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.

When using this product

- do not use more than directed

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 exceed 6 doses in a 24-hour period
- use enclosed dosage cup
- tsp = teaspoon, mL = milliliter

| age | dose |
|------------------------|-----------------------------|
| children 6 to 12 years | 2 tsp (10 ml) every 4 hours |
| children 4 to 6 years | 1 tsp (5 ml) every 4 hours |
| children under 4 years | do not use |

Other information

- each 5 mL contains: sodium 3 mg
- store at room temperature

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? 1-877-99 GENOM (43666)

Información del medicamento

Ingredientes activos Propósito

(en cada 5 mL, 1 cucharadita)
Dextrometorfano HBr, 5 mg.....Supresor de la tos
Guaifenesina, 50 mg.....Expectorante
Fenilefrina HCl, 2.5 mg.....Descongestionante nasal

Usos

- ayuda a aliviar la flema (mucosidad) y a adelgazar las secreciones bronquiales para drenar los conductos bronquiales
- alivia temporalmente los síntomas que se presentan con un resfriado:
 - congestión nasal
 - tos debido a irritación menor de garganta y bronquial

Advertencias

No les use en niños si está tomando un medicamento de prescripción inhibitor de la monoaminooxidasa (IMAO) (ciertos medicamentos para la depresión, condiciones psiquiátricas o emocionales o para la enfermedad de Parkinson), o las 2 semanas después de suspender medicamento IMAO. Si no sabe si su medicamento contiene un IMAO, pregunte a un médico o farmacéutico antes de tomar este producto.

Pregunte a un doctor antes de usar si el niño padece

- insuficiencia cardíaca
- hipertensión arterial
- diabetes
- enfermedad tiroidea



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

3
686975-3
8/17

TUKOL A

dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:50066-536

| | |
|--------------------------------|------|
| 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: HBR47K3TBD) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SORBITOL (UNII: 506T60A25R) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Product Characteristics

| | | | |
|-----------------|----------------------|---------------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | GRAPE (GRAPE FLAVOR) | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:50066-536-24 | 118 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/09/2014 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|----------------------|--|----------------------|--------------------|
| OTC mono graph final | part341 | 06/09/2014 | |

Labeler - Genomma Lab USA, Inc. (832323534)

Registrant - AptaPharma Inc. (790523323)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------|---------|-----------|------------------------|
| AptaPharma Inc. | | 790523323 | manufacture(50066-536) |

Revised: 12/2017

Genomma Lab USA, Inc.