

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

Tukol® Honey Children Cough & Congestion

Drug Facts

<i>Active ingredients (in each 2.5 mL)</i>	<i>Purpose</i>
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.

Do not exceed recommended dosage.

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.

Directions

- do not exceed 6 doses in a 24-hour period
- measure only with dosing cup provided
- keep dosing cup with product
- mL = milliliter

age	dose
children 6 to under 12 years	5 mL every 4 hours
children 4 to under 6 years	2.5 mL every 4 hours
children under 4 years	do not use

Other information

- each 2.5 mL contains: **sodium 1 mg**
- store at 15-30°C (59-86°F). Do not refrigerate.

Inactive ingredients

anhydrous citric acid, FD&C yellow # 6, flavor, glycerin, honey, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

Questions or comments?

1-877-994-3666

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

PRINCIPAL DISPLAY PANEL - 118 ml Bottle Carton

Tukol®

HONEY CHILDREN
MIEL NIÑOS

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®

HONEY CHILDREN
MIEL NIÑOS

COUGH & CONGESTION
TOS Y CONGESTIÓN

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

Ages /
Edades
4+

SABOR A MIEL

NATURAL
HONEY
FLAVOR

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)

Directions

- do not take more than 6 doses in any 24 hour period
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- keep dosing cup with product • mL = milliliter

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Información del Medicamento

Ingredientes activos Propósitos (en cada 2.5 mL)

Dextrometorfano HBr, 5 mg.....Supresor de la Tos
Guaifenesina, 50 mg.....Expectorante
Fenilefrina HCl, 2.5 mg.....Descongestionante Nasal

Usos

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

Advertencias

No lo use en un niño que esté tomando un inhibidor de la monoamina oxidasa (MAOI) recetado (ciertos medicamentos para la depresión, condiciones psiquiátricas o emocionales o para la enfermedad de Parkinson), o durante 2 semanas después de suspender el medicamento IMAO. Si no sabe si el medicamento recetado de su niño contiene un IMAO, consulte a un médico o farmacéutico antes de administrar este producto.

Información del Medicamento (continuación)

Consulte a su médico si el niño padece

- insuficiencia cardíaca
- hipertensión arterial
- diabetes
- enfermedad tiroidea
- tos duradera o crónica, tal como ocurre con el asma
- tos que se produce con mucha flema (mucosidad)

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

No exceder la dosis recomendada.

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 Envenenamiento (1-800-222-1222).

Instrucciones

- no exceder 6 dosis en un periodo de 24 horas
- medir solo con la copa dosificadora incluida
- mantenga la copa dosificadora con este producto
- mL = mililitros

edad	dosis
niños 6 a menores de 12 años	5 mL cada 4 horas
niños 4 a menores de 6 años	2.5 mL cada 4 horas
niños menores de 4 años	no usar

Información adicional

- cada (2.5 mL) contiene: sodio 1 mg
- almacenar entre 15-30 °C (59-86 °F). No refrigerar.

Ingredientes inactivos ácido cítrico anhidro, FD&C amarillo # 6, sabor, glicerina, miel, propilenglicol, agua purificada, benzoato de sodio, sorbitol, sucralosa, goma de xantano

¿Preguntas o comentarios? 1-877-994-3666

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



Rev 1 2000008887



LOT No. / LOTE:
EXP:

BX - 106

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COUGH & CONGESTION

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- CHEST CONGESTION

4 FL OZ (118 ml)

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-301
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 YELLOW NO. 6 (UNII: H77VEI93A8)	
HONEY (UNII: Y9H1V576FH)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Sorbitol (UNII: 506T60A25R)	
Xanthan gum (UNII: TTV12P4NEE)	
Sucralose (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	YELLOW (Amber to yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-301-04	1 in 1 CARTON	02/09/2020	
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	02/09/2020	

Labeler - Genomma Lab USA (832323534)

Revised: 1/2024

Genomma Lab USA