

**TUKOL CHILDRENS COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride syrup  
Genomma Lab USA**

*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.*

-----

**Tukol® Children's Cold & Flu**

**Drug Facts**

<b>Active ingredients (in each 10 mL or 2 teaspoonful)</b>	<b>Purpose</b>
<b>Acetaminophen 325 mg</b>	<b>Pain reliever/fever reducer</b>
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses**

Temporarily relieves these common cold and flu symptoms:

- nasal congestion
- cough
- minor aches and pains
- sore throat
- headache
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

**Warnings**

**Liver warning**

This product contains acetaminophen. Severe liver damage may occur if your child takes:

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen.

**Allergy alert**

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters

- rash. If skin reaction occurs, stop use and seek medical help right away.

### **Sore throat warning**

If sore throat is severe, persists more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly

### **Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- for 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 giving this product.

### **Ask a doctor before use if the child has**

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- persistent or chronic cough 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 the blood thinning drug warfarin.

### **When using this product**

- **do not exceed recommended dose (see overdose warning)**

### **Stop use and ask a doctor if**

- nervousness, dizziness or sleeplessness occur
- redness or swelling is present
- pain, nasal congestion or cough gets worse or lasts more than 5 days
- new symptoms occur
- fever gets worse or lasts more than 3 days
- cough comes back, or occurs with rash or headache that lasts

These could be signs of a serious condition.

**Keep out of reach of children.**

### **Overdose warning**

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

## Directions

- **do not give more than directed (see Overdose warning)**
- **product not labeled with directions or warnings for adult use**
- do not give more than 5 doses in any 24-hour period
- do not give more than 5 days unless directed by a doctor
- measure only with dosing cup provided
- dose as follows or as directed by a doctor
- mL=milliliter, tsp=teaspoonful as bulleted statement.

<b>Age</b>	<b>Dose</b>
Children 6 to under 12 years of age	10 mL or 2 tsp every 4 hours
Children under 6 years of age	do not use

## Other information

- each 10 mL contains: **sodium 6 mg**
- store between 20-25°C (68-77°F), do not refrigerate
- keep carton for complete Drug facts

## Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C Blue #1, FD&C Red #40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

## Questions?

**Call 1-877-994-3666**

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

## PRINCIPAL DISPLAY PANEL - 118 ml Bottle Carton

NEW LOOK

Tukol®  
CHILDREN'S  
COLD & FLU

Acetaminophen / Dextromethorphan  
HBr / Guaifenesin/Phenylephrine HCL

Ages  
6-11

flavor

## BERRIES

Relieves:

- MINOR ACHES & PAIN
- FEVER
- NASAL & CHEST CONGESTION
- COUGH

4 FL OZ (118 ml)

# Tukol<sup>®</sup>

CHILDREN'S  
NIÑOS

DO NOT USE IF PRINTED SEAL UNDER CAP  
IS TORN OR MISSING  
NO SE USE SI EL SELLO IMPRESO DEBAJO DE LA TAPA  
ESTAROTO OFALTA

1 1/4

NEW LOOK / NUEVA IMAGEN

# Tukol<sup>®</sup>

CHILDREN'S  
NIÑOS

**COLD & FLU**  
**GRIPA Y RESFRIADO**

Acetaminophen / Dextromethorphan  
HBr / Guaifenesin/Phenylephrine HCL  
Acetaminofèn / Dextrometorano  
/ Guaifenesina / Fenilefrina

Ages  
Edades  
6-11



Relieves/Alivia:

- MINOR ACHES & PAIN / DOLORES Y MOLESTIAS MENORES
- FEVER / FIEBRE
- NASAL & CHEST CONGESTION / CONGESTIÓN DE PECHO Y NASAL

### Drug Facts

**Active ingredients** **Purpose**  
(in each 10 mL or 2 teaspoonful)

Acetaminophen 325 mg.....Pain reliever/fever reducer  
Dextromethorphan HBr 10 mg.....Cough suppressant  
Guaifenesin 200 mg.....Expectorant  
Phenylephrine HCl 5 mg.....Nasal decongestant

**Uses** Temporarily relieves these common cold and flu symptoms: • nasal congestion • cough • minor aches and pains • sore throat • headache • temporarily reduces fever • helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

### Warnings

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if your child takes: • more than 5 doses in 24 hours, which is the maximum daily amount • with other drugs containing acetaminophen.

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include: • skin reddening • blisters • rash. If skin reaction occurs, stop use and seek medical help right away.

**Sore throat warning:** If sore throat is severe, persists more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly

**Do not use** • with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

• for 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 giving this product.

### Ask a doctor before use if the child has

- liver disease • heart disease • high blood pressure
- thyroid disease • diabetes
- persistent or chronic cough 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 the blood thinning drug warfarin.**

**When using this product • do not exceed recommended dose (see overdose warning)**

**Stop use and ask a doctor if** • nervousness, dizziness or sleeplessness occur • redness or swelling is present • pain, nasal congestion or cough gets worse or lasts more than 5 days • new symptoms occur • fever gets worse or lasts more than 3 days • cough comes back, or occurs with rash or headache that lasts These could be signs of a serious condition.

**Keep out of reach of children.**

**Overdose warning** Taking more than the recommended

COUGH / TOS

4 FL OZ (118 ml)

dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a



LOT No. / LOTE  
Exp. / Exp.

5/16

**Drug Facts (continued)**

Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

**Directions** • do not give more than directed (see Overdose warning)

- product not labeled with directions or warnings for adult use
- do not give more than 5 doses in any 24-hour period
- do not give more than 5 days unless directed by a doctor
- measure only with dosing cup provided
- dose as follows or as directed by a doctor
- mL=milliliter, tsp=teaspoonful as bulleted statement.

Age	Dose
Children 6 to under 12 years of age	10 mL or 2 tsp every 4 hours
Children under 6 years of age	do not use

**Other information** • each 10 mL contains: sodium 6 mg • store between 20-25°C (68-77°F), do not refrigerate • keep carton for complete Drug facts

**Inactive ingredients** anhydrous citric acid, edetate disodium, FD&C Blue #1, FD&C Red #40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

**Questions?** Call 1-877-994-3666

**Información del medicamento (continuación)**

**No usar** • Con ningún otro fármaco que contenga acetaminofén (recetado o de venta libre). Si no se está seguro si el fármaco contiene acetaminofén, consultar a un médico o farmacéutico.

• En niños que estén tomando inhibidores de la monoaminooxidasa (MAO) recetados (ciertos fármacos para la depresión, afecciones psiquiátricas o emocionales, o la enfermedad de Parkinson) o durante 2 semanas después de interrumpir el fármaco IMAO. Si no sabe si el fármaco recetado a su hijo contiene un IMAO, consultar a un médico o farmacéutico antes de administrar este producto.

**Preguntar a un médico antes de usar si su hijo tiene**

- enfermedad hepática • enfermedad cardíaca
- hipertensión • enfermedad tiroidea • diabetes
- tos persistente o crónica como sucede con el asma
- tos que se presenta con demasiada flema (moco).

**Consultar a un médico o farmacéutico antes de usar, si su hijo está tomando el fármaco anticoagulante warfarina.**

**Al utilizar este producto, no exceder la dosis recomendada (ver advertencia de sobredosis).**

**Suspender el uso y preguntar a un médico si:**

- ocurre nerviosismo, mareos o insomnio
- hay enrojecimiento o hinchazón
- el dolor, la congestión nasal o la tos empeora o dura más de 5 días • se presentan nuevos síntomas
- la fiebre empeora o dura más de 3 días
- la tos regresa u ocurre con sarpullido o dolor de cabeza que permanece. Estos podrían ser signos de una afección grave.

5/8  
N.C.

Glue

**Información del medicamento**

**Ingredientes activo Propósito**  
(en cada 10 mL o 2 cucharaditas)

Acetaminofén 325 mg.....Analgésico/anti febril  
Dextrometorfano HBr 10 mg.....Inhibidor de la tos  
Guaifenesina 200 mg.....Expectorante  
Hidrocloruro de fenilefrina 5 mg.....Descongestivo nasal

**Usos** Alivia temporalmente los siguientes síntomas del resfriado común y la gripe:  
• congestión nasal • tos • dolores y molestias leves  
• dolor de garganta • dolor de cabeza  
• reduce temporalmente la fiebre  
• Ayuda a aflojar la flema (moco) y a reducir secreciones de las vías respiratorias, eliminando el moco molesto y generando tos más productiva.

**Advertencias**  
Advertencia acerca del hígado: Este producto contiene acetaminofén. Puede producirse daño hepático grave si su hijo toma: • más de 5 dosis en 24 horas, que es la cantidad diaria máxima • con otros fármacos que contengan acetaminofén.  
**Alerta sobre alergia:** el acetaminofén puede provocar reacciones graves en la piel. Los síntomas pueden incluir: • enrojecimiento de la piel • ampollas • sarpullido. Si se produce una reacción en la piel, suspender el uso y buscar ayuda médica de inmediato.  
**Advertencia acerca del dolor de garganta:** Si el dolor de garganta es intenso, persiste por más de 2 días, está acompañado o seguido de fiebre, dolor de cabeza, sarpullido, náuseas o vómitos, consultar a un médico de inmediato. ▶

Mantener fuera del alcance de los niños. Advertencia de sobredosis Tomar más de la dosis recomendada (sobredosis) puede provocar daño hepático. En caso de sobredosis, buscar ayuda médica o comunicarse con un centro de toxicología (1-800-222-1222) de inmediato. La atención médica rápida es fundamental aunque no se adviertan signos ni síntomas.

**Instrucciones**

- No administrar más de lo indicado (ver advertencia de sobredosis).
- No administrar más de 5 dosis en un periodo de 24 horas.
- No administrar durante más de 5 días a menos que lo indique un médico • Medir solo con el vaso dosificador suministrado.
- No usar el vaso dosificador con otros productos.
- Administrar dosis según se indica a continuación o según las indicaciones de un médico
- mL=millilitro, tsp=teaspoonful

Edad	Dosis
Niños 6 a 12 años de edad	10 mL o 2 cucharaditas cada 4 horas
Niños menores de 6 años de edad	no usar

**Información adicional** • Cada 10 ml contienen: sodio 6 mg • Almacenar a 20-25° C (68-77 °F), no refrigerar  
• Mantenga cajilla para obtener la información del Medicamento

**Ingredientes inactivos** ácido cítrico anhidro, edetato disódico, azul brillante FCF, rojo allura AC, sabores, glicerina, propilenglicol, galato de propilo, agua purificada, benzoato de sodio, sorbitol, sacarosa, goma xantana

**¿Preguntas? Llame 1-877-994-3666**

Distributed by / Distribuido por:  
Genomma Lab USA Inc. Houston, TX 77027 BX 057 rev. 01

2FTJNRYGEWW11 V-2

**TUKOL CHILDRENS COLD AND FLU**

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride syrup

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50066-315
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

<b>Acetaminophen</b> (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	32.5 mg in 1 mL
<b>Dextromethorphan Hydrobromide</b> (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	1.0 mg in 1 mL
<b>Guaifenesin</b> (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	20.0 mg in 1 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.5 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>Glycerin</b> (UNII: PDC6A3C00X)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>Sorbitol</b> (UNII: 506T60A25R)	
<b>Sodium benzoate</b> (UNII: OJ245FE5EU)	
<b>Sucralose</b> (UNII: 96K6UQ3ZD4)	

### Product Characteristics

<b>Color</b>	BLUE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-315-04	1 in 1 CARTON	01/17/2023	
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 final	part341	01/17/2023	

**Labeler** - Genomma Lab USA (832323534)