

**CHILDRENS TUKOL MULTI-SYMPATOM COLD AND FLU- acetaminophen,
dextromethorphan hydrobromide, guaifenesin, phenylephrine
hydrochloride liquid
Genomma Lab USA, Inc.**

Children's Tukol Multi-Symptom Cold & Flu 519

Drug Facts

Active ingredients

(in each 10 mL = 2 teaspoonful)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCL 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Expectorant

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 non prescription). If you are not sure whether a drug contained 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 an MAOI drug. If you do not know if 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 section).**

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.

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

- **this product does not contain directions or complete warning for adult use**
- **do not give more than directed (see Overdose warning)**
- do not give more than 5 doses in any 24-hour period
- do not give for 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 = teaspoon
- dose as follows

age	dose
children 6 to under 12 years of age	2 teaspoons (10 mL) every 4 hours
children under 6 years of age	do not use

Other information

- each teaspoon 10 mL contains: sodium 5 mg
- store between 15-30°C (59-86°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, orbitol, sucralsoe, xanthan gum

Questions?

Call 1-877-994-3666

Children's Tukul Multi-Symptom Cold & Flu product label


Tukol[®]

CHILDREN'S NIÑOS

COLD & FLU GRIPE Y RESFRIADO

Acetaminophen 325 mg / Dextromethorphan HBr 10 mg
Guaifenesin 200 mg / Phenylephrine HCl 5 mg
Acetaminofén 325 mg / Dextrometorfano HBr 10 mg
Guaifenesina 200 mg / Fenilefrina HCl 5 mg

Ages/
Edades
6-11



Relieves/Alivia:

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

4 FL OZ (118 mL)

Drug Facts

Active ingredients (in each 10 mL or 2 teaspoons)

Purposes

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

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- 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

- 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

- 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 occurs
- 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.

Drug Facts (continued)

Quick medical attention is critical even if you do not notice any signs or symptoms.

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children under 6 years of age	do not use

Other information

- each teaspoon (10 mL) contains: sodium 5 mg
- store between 15-30°C (59-86°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 or comments? Call 1-877-994-3666

Información del Medicamento

Ingredientes activos Propósitos (en cada 10 mL o 2 cucharaditas)

Acetaminofén, 325 mg.....Analgésico/antifebril

Dextrometorfano HBr, 10 mg.....Supresor de la tos

Guaifenesina, 200 mg.....Expectorante

Fenilefrina HCl, 5 mg.....Descongestionante nasal

Usos

- alivia temporalmente los 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 desprender la flema (mucosidad) y a adelgazar las secreciones bronquiales para drenar las vías respiratorias y generar 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.

Información del Medicamento (continuación)

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

Consulte a su médico antes de usar si el niño padece

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

Consulte a su médico o farmacéutico antes de usarlo, si el niño está tomando el fármaco anticoagulante warfarina.

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

Suspender su uso y consulte a su médico si

- presenta 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 condición grave.

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

- este producto no contiene instrucciones o advertencias completas para el uso en adultos
- no administrar más de lo indicado (ver advertencia de sobredosis)
- no administrar más de 5 dosis en un período de 24 horas
- no administrar durante más de 5 días a menos que lo indique un médico
- medir solo con la copa dosificadora incluida
- mL = mililitro
- TSP = cucharadita
- administrar dosis según se indica a continuación

edad	dosis
niños de 6 a 12 años de edad	2 cucharaditas (10 mL) cada 4 horas
niños menores de 6 años de edad	no usar

Información adicional

- cada cucharadita (10 mL) contiene: sodio 5 mg
- almacenar a 15-30°C (59-86 °F)
- no refrigerar
- conserve la caja para información completa del medicamento.

Ingredientes inactivos ácido cítrico anhidro, edetato disódico, FD&C azul #1, FD&C rojo #40, sabores, glicerina, propilenglicol, galato de propilo, agua purificada, benzoato de sodio, sorbitol, sucralosa, goma xantana.

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

Distributed by / Distribuido por: Genomma Lab USA Inc., Houston, TX 77098 BX-057 rev. 01

KEEP CARTON FOR COMPLETE DRUG FACTS

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

Tukol[®]

Childrens

COLD & FLU

Acetaminophen 325 mg/Dextromethorphan HBr 10 mg/Guaifenesin 200 mg/Phenylephrine HCL 5 mg

Ages 6-11

Relieves

Minor Aches & Pain

Fever

Nasal & Chest Congestion

4 FL OZ (118 mL)

Distributed By

Genomma Lab USA Inc. Houston, TX 77098

CHILDRENS TUKOL MULTI-SYMPATOM COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-519
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 10 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 10 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-519-24	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2016	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC Monograph Drug	M012	05/04/2016	

Labeler - Genomma Lab USA, Inc. (832323534)

Registrant - Genomma Lab USA, Inc. (832323534)

Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(50066-519)

Establishment

Name	Address	ID/FEI	Business Operations
Rnv LLC		118917568	manufacture(50066-519)

Revised: 1/2024

Genomma Lab USA, Inc.