## 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**

Active ingredients (in each 10 mL or 2 teaspoonful)	Purpose
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 vomitting, 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.

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

#### **Ouestions?**

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**

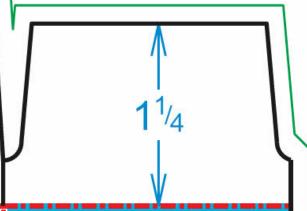
#### Relieves:

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

4 FL OZ (118 ml)



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



**NEW LOOK / NUEVA IMAGEN** 

# CHILDREN'S NIÑOS

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

Acetaminophen / Dextromethorphan HBr / Guaifenesin/Phenylephrine HCL Acetaminofén / Dextrometorfano / Guaifenesina / Fenilefrina

Ages Edades 6-11



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 HCI 5 mg......Nasal decongestant

Uses Temporarily relieves these common cold and flu nasal congestion symptoms: cough headache

aches and pains sore throat · temporarily reduces fever

 helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

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

· 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 vomitting, 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

- heart disease liver 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

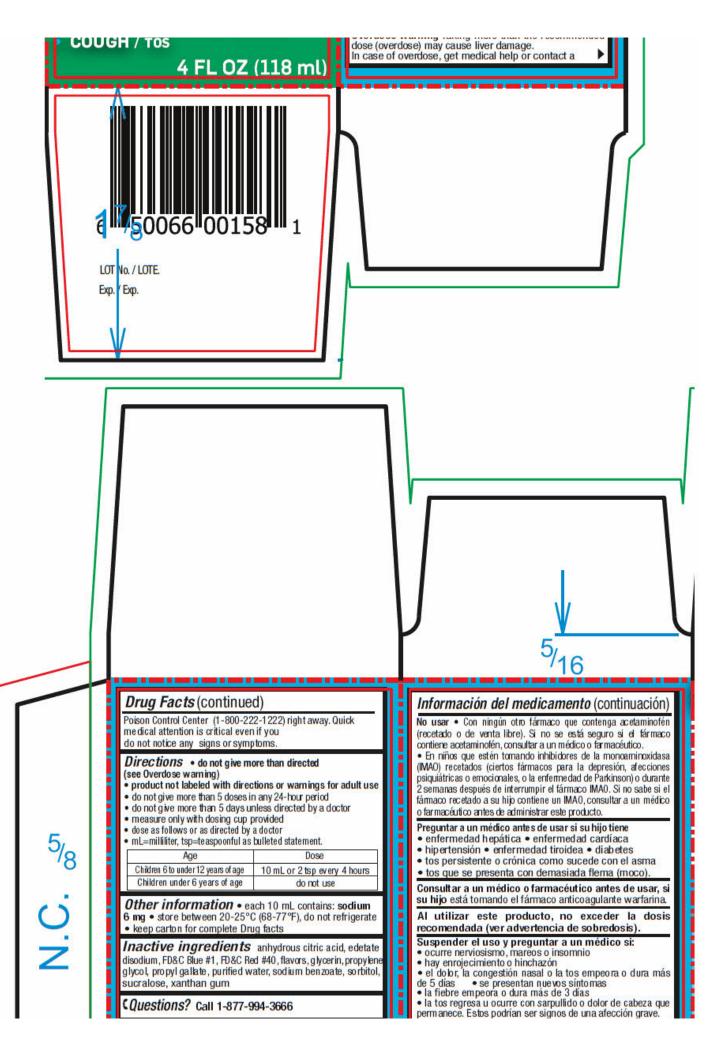
or sleeplessness occur. redness or swelling is present · pain, nasal congestion or cough gets worse or lasts more than 5 days

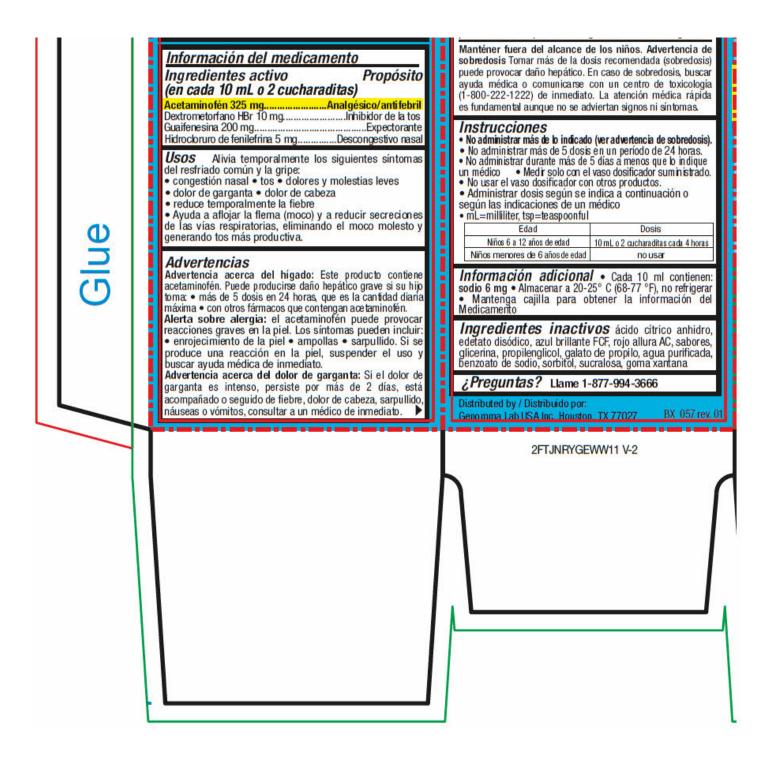
more than 5 days • new symptoms occur • fever gets worse or lasts more than 3 days

 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





#### TUKOL CHILDRENS COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride syrup

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (S	Source)	NDC:500	066-315
Route of Administration	ORAL				
Active Ingredient/Active Moiety					
Ingredient Name		Basis of Stre	ength	Strength	

Acetaminophen (UNII: 36209ITL9D) (Acetaminophen - UNII:36209ITL9D)	Acetaminophen	32.5 mg in 1 mL
<b>Dextromethorphan Hydrobromide</b> (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	1.0 mg in 1 mL
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	20.0 mg in 1 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.5 mg in 1 mL

Inactive Ingredients					
Ingredient Name	Strength				
WATER (UNII: 059QF0KO0R)					
Glycerin (UNII: PDC6A3C0OX)					
Propylene Glycol (UNII: 6DC9Q167V3)					
Sorbitol (UNII: 506T60A25R)					
Sodium benzoate (UNII: OJ245FE5EU)					
Sucralose (UNII: 96K6UQ3ZD4)					

Product Characteristics			
Color	BLUE	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

F	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)

Revised: 1/2023 Genomma Lab USA