

TUKOL MAX ACTION COLD, FLU AND SORE THROAT- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride syrup
Genomma Lab USA

Tukol® Max Action Cold, Flu and Sore Throat

Drug Facts

<i>Active ingredients (in each 20 mL)</i>	<i>Purposes</i>
Acetaminophen 650mg	Pain reliever/fever reducer
Dextromethorphan HBr 20 mg	Cough suppressant
Guaifenesin 400 mg	Expectorant
Phenylephrine HCl 10 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 you take:

- more than 4 doses (20 mL each) in 24 hours, which is the maximum daily amount for this product.
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product.

Allergy alert

Acetaminophen may cause severe skin reactions. Symptoms may include: skin reddening, blisters and rash.

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

Sore throat warning

if sore throat is severe, persists for 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
- if you are 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 you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- a breathing problem such as chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma chronic, bronchitis or emphysema
- cough that occurs with too much phlegm (mucus)
- trouble urinating due to enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

When using this product do not use more than directed

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- pain, nasal congestion or cough gets worse or lasts more than 7 days
- cough comes back or occurs with fever, rash, or headache that lasts
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur.

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

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

Directions

- **do not take more than directed**
- Do not take more than 4 doses in 24 hours.

- This adult strength product is not intended for use in children under 12 years of age
- Dose as follows or as directed by a doctor
- Use dose cup provided

age	dose
adults and children 12 years and older	20 mL every 4 hours
children under 12 years of age	do not use

Other information

- each 20 mL contains: **sodium 10 mg**
- store between 15-30°C (59-86°F), do not refrigerate

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?

1-877-994-3666

Monday to Friday from 8 AM to 6 PM, Central time.

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

PRINCIPAL DISPLAY PANEL - 177 mL Bottle Carton

Tukol®

MAX ACTION

COLD, FLU AND SORE THROAT

Acetaminophen / Dextromethorphan HBr/
Guaifenesin / Phenylephrine HCl

Ages
12+

MAX
STRENGTH

Relieves:

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

- COUGH

6 FL OZ (177 mL)

Tukol[®]

MAX ACTION

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[®]

MAX ACTION

COLD, FLU AND SORE THROAT

**GRIPE, RESFRIADO Y
DOLOR DE GARGANTA**

**Acetaminophen / Dextromethorphan HBr/
Guaifenesin / Phenylephrine HCl**
**Acetaminofén / Dextrometorfano HBr/
Guaifenesina / Fenilefrina HCl**

**Ages/Edades
12+**

**MAX
STRENGTH/
MÁXIMA
POTENCIA**



Drug Facts

Active ingredients (in each 20 mL)	Purposes
Acetaminophen, 650 mg.....	Pain reliever/Fever reducer
Dextromethorphan HBr, 20 mg.....	Cough suppressant
Guaifenesin, 400 mg.....	Expectorant
Phenylephrine HCl, 10 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 you take:
- more than 4 doses (20 mL each) in 24 hours, which is the maximum daily amount for this product
 - with other drugs containing acetaminophen
 - 3 or more alcoholic drinks daily while using this product.
- Allergy alert:** acetaminophen may cause severe skin reactions. Symptoms may include: skin reddening, blisters and rash. If skin reaction occurs, stop use and seek medical help right away.
- Sore throat warning:** if sore throat is severe, persists for 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 ■ if you are 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 you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- breathing problem such as chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough that occurs with too much phlegm (mucus)
- trouble urinating due to enlarged prostate gland.

Ask a doctor or pharmacist before use if you are

Relieves/Alivia:

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

6 FL OZ (177 mL)

Read a copy of the package insert before use if you are taking the blood thinning drug warfarin.

When using this product do not use more than directed.

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- symptoms do not get better within 7 days or are accompanied by fever
- cough comes back or occurs with fever, rash, or persistent headache
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

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

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Genomina Lab.®

Drug Facts (continued)

Directions

- do not take more than directed
- do not take more than 4 doses in any 24 hours
- this adult strength product is not intended for use in children under 12 years of age
- measure only with dosing cup provided
- keep dosing cup with product
- mL = milliliter
- dose as follows

age	dose
adults and children 12 years of age and older	20 mL every 4 hours
children under 12 years of age	do not use

Other information

- each (20 mL) contains: sodium 10 mg
- store between 15-30°C (59-86°F) ■ do not refrigerate.

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.

Información del Medicamento (continuación)

Consulte a su médico antes de usar si padece

- enfermedad hepática ■ enfermedad cardíaca
- hipertensión ■ enfermedad tiroidea ■ diabetes
- problemas respiratorios como bronquitis crónica
- tos persistente o crónica tal como ocurre con el tabaquismo, asma, bronquitis crónica o enfisema
- tos que se presenta con exceso de flema (mucosidad) ■ dificultad para orinar debido al agrandamiento de la próstata.

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

Cuando use este producto, no use más de lo indicado.

Suspenda su uso y consulte a su médico si

- siente nerviosismo, mareos o insomnio
- los síntomas no mejoran en los siguientes 7 días o están acompañados de fiebre
- la tos regresa u ocurre con fiebre, sarpullido, o dolor de cabeza persistente
- la fiebre empeora o dura más de 3 días
- hay enrojecimiento o hinchazón
- se presentan nuevos síntomas.

Questions or comments? 1-877-994-3666 Monday to Friday
from 8 am to 6 pm, Central Time.

Información del Medicamento

Ingredientes activos (en cada 20 mL)

Propósitos

Acetaminofén, 650 mg.....	Analgésico/Antifebril
Dextrometorfano HBr, 20 mg.....	Inhibidor de la tos
Guafenesina, 400 mg.....	Expectorante
Fenilefrina HCl, 10 mg.....	Descongestionante nasal

Usos

- alivia temporalmente los síntomas de 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 toma: ■ más de 4 dosis (de 20 mL cada una) en 24 horas, la cual es la cantidad diaria máxima para este producto ■ con otros fármacos que contengan acetaminofén ■ 3 o más bebidas alcohólicas diarias mientras usa este producto.

Alerta sobre alergia: el acetaminofén puede provocar reacciones severas en la piel. Los síntomas pueden incluir lo siguiente: enrojecimiento de la piel, ampollas y sarpullido. Si se produce una reacción en la piel, suspender el uso y busque 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.

No utilizarlo ■ con ningún otro fármaco que contenga acetaminofén (recetado o de venta libre). Si no se está seguro si el fármaco contiene acetaminofén, preguntar a un médico o farmacéutico ■ si está tomando inhibidores de la monoamino oxidasa (IMAO) 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 contiene un IMAO, preguntar a un médico o farmacéutico antes de tomar este producto.

Estos podrían ser signos de una afección grave.

Si está embarazada o lactando, preguntar a un profesional de la salud antes de usar.

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 de inmediato. La atención médica rápida es fundamental aunque no se adviertan signos ni síntomas.

Indicaciones

- no tomar más de lo indicado
- no tome más de 4 dosis en un período de 24 horas
- este producto de concentración para adultos no está diseñado para usarse en niños menores de 12 años
- medir solo con la copa dosificadora incluida
- mantenga la copa dosificadora con este producto
- mL = mililitro
- administrar dosis según se indica a continuación

edad	dosis
adultos y niños de 12 años de edad y mayores	20 mL cada 4 horas
niños menores de 12 años	no usar

Otra información

- cada (20 mL) contiene: sodio 10 mg
- almacenar entre 15 - 30°C (59-86°F)
- no refrigerar.

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?

1-877-994-3666 Lunes a viernes de 8 am a 6 pm,
Hora del Centro.

Distributed by / Distribuido por:
Genomma Lab USA Inc.,
Houston, TX 77098
BX-063 Rev. 01

Rev. 1



EXP:

LOT No./LOTE:

TUKOL MAX ACTION COLD, FLU AND SORE THROAT

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-313
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	32.5 mg in 1 mL
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	1 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	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	MENTHOL (Characteristic medicinal)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-313-06	1 in 1 CARTON	06/21/2024	
1		177 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
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OTC monograph drug M012

06/21/2024

Labeler - Genomma Lab USA (832323534)

Revised: 6/2024

Genomma Lab USA