

TUKOL MAX ACTION SINUS LIQUID- acetaminophen, 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® Max Action Sinus Liquid

Drug Facts

Active ingredients (in each 20 mL)	Purposes
Acetaminophen 650mg	Pain reliever
Guaifenesin 400 mg	Expectorant
Phenylephrine HCl 10 mg	Nasal decongestant

Uses

temporarily relieves:

- nasal congestion
- headache
- minor aches and pains
- sinus congestion and pressure
- temporarily promotes nasal and sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

Warnings

Liver warning

This product contains acetaminophen.

Severe liver damage may occur if you take:

- more than 6 doses in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert

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

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

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 now 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.
- for children under 12 years of age

Ask a doctor before use if you have

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

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

- nervousness, dizziness or sleeplessness occur
- redness or swelling is present
- symptoms do not get better within 7 days or are accompanied by a fever
- fever gets worse or lasts more than 3 days
- new symptoms occur
- cough lasts more than 7 days, comes back, or occurs with fever, rash or persistent headache. 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 for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- take only as recommended (see Overdose warning)
- use dosage cup
- mL = milliliter
- do not take more than 6 doses in any 24-hour period

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
- dosage cup provided
- store between 15-30°C (59-86°F)
- do not refrigerate

Inactive ingredients

Anhydrous citric acid, edetate disodium, FD&C yellow no. 6, flavor, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

Questions?

Call weekdays from 8 AM to 6 PM EST at 1-877-994-3666

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

PRINCIPAL DISPLAY PANEL - 177 ml Bottle Carton

NEW

Tukol®

MAX ACTION

SINUS

Headache and Congestion

Acetaminophen / Guaifenesin / Phenylephrine HCl

For Ages
12 & Over

NATURAL
GINGER FLAVOR

- ◆ SINUS CONGESTION
- ◆ HEADACHE
- ◆ EXPECTORANT

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

NEW / NUEVO

Tukol[®]

MAX ACTION

SINUS

Headache and Congestion
Dolor de Cabeza y Congestión

Acetaminophen / Guaifenesin / Phenylephrine HCl
Acetaminofén / Guaifenesina / Fenilefrina HCl

For Ages
12 & Over/
Edades 12+



- SINUS CONGESTION / PRESIÓN DE LOS SENOS NAALES
- HEADACHE / DOLOR DE CABEZA

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Lorem

HEADACHE / DOLOR DE CABEZA

EXPECTORANT / EXPECTORANTE

6 FL OZ (177 ml)



LOT No. / LOTE.

Exp. / Exp.

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Drug Facts (continued)

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Información del Medicamento (continuación)

Preguntar a un médico antes de usar si usted tiene:

- enfermedad hepática ■ enfermedad cardíaca
- enfermedad tiroidea ■ presión arterial alta
- diabetes ■ dificultad para orinar debido a agrandamiento de la próstata. ■ tos persistente o crónica como sucede al fumar, con el asma o enfisema
- tos que se presenta con demasiada flema (mucosidad)

Preguntar a un médico o farmacéutico antes de usar: si está tomando el medicamento anticoagulante warfarina.

Al utilizar este producto no usar más de lo indicado (ver advertencia de sobredosis)

Suspender el uso y consulte a su médico si

- ocurre nerviosismo, mareos o insomnio
- hay enrojecimiento o hinchazón
- los síntomas no mejoran en un plazo de 7 días o están acompañados por fiebre
- la fiebre empeora o dura más de 3 días
- se presentan nuevos síntomas
- la tos dura más de 7 días, regresa, ocurre fiebre, sarpullido o dolor de cabeza que permanece. 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

Información del Medicamento

Ingredientes activos
(en cada cucharadita de 20 ml)

Acetaminofén 650 mg	Analgésico
Guaifenesina 400 mg.....	Expectorante
Fenilefrina HCl 10 mg.....	Descongestivo nasal

Propósito

Usos
Alivia temporalmente:

- congestión nasal ■ dolor de cabeza ■ Dolores y molestias leves ■ congestión y presión de los senos nasales ■ favorece temporalmente el drenaje nasal y sinusal
- ayuda a aflojar la flema (moco) hace la tos más productiva para eliminar el moco de las vías bronquiales

Precauciones
Advertencia acerca del hígado Este producto contiene Acetaminofén. Puede producirse daño hepático grave si toma: ■ más de 6 dosis en 24 horas que es la cantidad máxima en este producto ■ con otros medicamentos 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

No usar ■ con ningún otro medicamento que contenga Acetaminofén (recetado o de venta libre). Si no está seguro si el medicamento contiene acetaminofén, preguntar a un médico o farmacéutico. ■ Si está tomando un medicamento de prescripción inhibidor de la monoaminooxidasa (IMAO) (ciertos medicamentos para la depresión, afecciones psiquiátricas o emocionales, o la enfermedad de Parkinson) o durante 2 semanas después de interrumpir el medicamento IMAO. Si no sabe si su medicamento recetado contiene un IMAO, preguntar a un médico o farmacéutico antes de administrar este producto. ■ niños menores de 12 años

Advertencia de sobredosis: Tomar más de la dosis recomendada (sobredosis) puede causar daño hepático. En caso de sobredosis accidental, obtenga ayuda médica o comuníquese con un Centro de Control de Envenenamiento de inmediato. La atención médica inmediata es crítica tanto para adultos como para niños, incluso si no nota algún signo o síntoma.

Instrucciones

- No administrar más de lo indicado (ver advertencia de sobredosis).
- utilice la taza medidora
- mL = mililitros
- no exceda 6 dosis en 24 horas

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

Otra Información

- contenido de sodio por cada 20 ml: 10 mg
- contiene la taza medidora
- almacenar a temperatura de 15-30°C (59-86°F)
- no refrigerar

Ingredientes inactivos Ácido cítrico anhidro, edetato disódico, FD&C amarillo no. 6, saborizante, glicerina, propilenglicol, galato de propilo, agua purificada, benzoato de sodio, sorbitol, sucralosa, goma xantana

¿Preguntas? 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 77027 BX-129

TUKOL MAX ACTION SINUS LIQUID

acetaminophen, guaifenesin, and phenylephrine hydrochloride syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-305
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
		22.5 mg

Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	32.5 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	YELLOW (Amber to yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-305-06	1 in 1 CARTON	07/30/2021	
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
OTC MONOGRAPH FINAL	part341	07/30/2021	

Labeler - Genomma Lab USA (832323534)

Revised: 8/2021

Genomma Lab USA