TUKOL HONEY NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate syrup
Genomma Lab USA

Tukol ®Honey Nighttime Cold & Flu

Drug Facts

Active Ingredients (in each 30 mL)	***Purpose***
Acetaminophen 650 mg	Pain reliever/Fever reducer
Dextromethorphan HBr 30 mg	Cough suppressant
Doxylamine Succinate 12.5 mg	Antihistamine

Uses

Temporarily relieves these common cold and flu symptoms:
- sore throat
- headache
- minor aches and pain
- runny nose and sneezing
- cough due to minor throat and bronchial irritation
- temporarily reduces fever

Warnings

Liver warning

The product contains Acetaminophen. Severe liver damage may occur if you take
- more than 4 doses (30 mL) 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 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
- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor.
- 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.
- to make a child sleepy

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use

- if you are taking sedatives or tranquillizers
- if you are taking the blood thinning drug warfarin

When using this product

- do not use more than directed
- avoid alcoholic drinks
- excitability may occur, especially in children
- marked drowsiness may occur
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- 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 headache that lasts. 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 may cause serious health problems. 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

- 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 = mililiter
- TBSP = tablespoon
- dose as follows

age	dose
adults and children 12 years of age and over	30 mL (2 Tablespoons) every 6 hours
Children under 12 years of age	do not use

when using day time and night time prodcuts, carefully read each label to ensure correct dosing.

Other information

- Each 30 mL contains: sodium **18 mg**
- store between 15-30 ^{o}C (59-86 ^{o}F)
- do not refrigerate

Inactive ingredients

Citric acid, FD&C Yellow # 6, flavor, glycerin, honey, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose

Questions or comments?

1-877-994-3666

Monday to Friday 8 am to 6 pm, Central Time

Distributed by:
Genomma Lab USA Inc.,
Houston, TX 77098

PRINCIPAL DISPLAY PANEL - 118 ml Bottle Carton


Night Time/Noche
Tukol®
HONEY MULTI-SYMPTOM
MIEL MULTI-SÍNTOMA
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
Night Time/Noche
Tukol®
HONEY MULTI-SYMPTOM
MIEL MULTI-SÍNTOMA
COLD & FLU
GRIPE Y RESFRIADO
Acetaminophen / Dextromethorphan HBr / Doxylamine succinate
Acetaminofén / Dextrometorfano HBr / Succinato de doxilamina
Ages/Edades 12+
SABOR A MIEL
NATURAL HONEY FLAVOR
Relieves/Alivia:
• HEADACHE, SORE THROAT, FEVER / DOLOR DE CABEZA Y GARGANTA, FIEBRE
• MINOR ACHES AND PAINS / DOLORES Y MOLESTIAS MENORES
• SNEEZING, RUNNY NOSE / ESTORNUDO, SECRECIÓN NASAL
• COUGH / TOS
4 FL OZ (118 ml)
Drug Facts
Active Ingredients (in each 30 mL) Purposes
Acetaminophen, 650 mg ..... Pain reliever/Fever reducer
Dextromethorphan HBr, 30 mg ..... Cough suppressant
Doxylamine Succinate, 12.5 mg ..... Antihistamine
Uses
■ temporarily relieves these common cold and flu symptoms:
■ sore throat ■ headache ■ minor aches and pain
■ runny nose and sneezing
■ cough due to minor throat and bronchial irritation
■ temporarily reduces fever.
Warnings
Liver warning: this product contains acetaminophen. Severe liver damage may occur if you take:
■ more than 4 doses (30 mL each) 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 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 ■ for more than 10 days for pain unless directed by a doctor ■ for more than 3 days for fever unless directed by a doctor ■ 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 ■ to make a child sleepy.
Ask a doctor before use if you have
■ liver disease ■ glaucoma ■ cough that occurs with too much phlegm (mucus) ■ a breathing problem or chronic cough that lasts or as occurs with smoking, asthma chronic bronchitis or emphysema ■ trouble urinating due to an enlarged prostate gland.
Ask a doctor or pharmacist before use if you are ■ taking sedatives or tranquilizers ■ if you are taking the blood thinning drug warfarin.
When using this product
■ do not use more than directed
■ avoid alcoholic drinks
■ excitability may occur, especially in children
■ marked drowsiness may occur
■ be careful when driving a motor vehicle or operating machinery
■ alcohol, sedatives, and tranquilizers may increase drowsiness.
Stop use and ask a doctor if
■ 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 headache that lasts. 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.
Drug Facts (Continued)
Overdose warning: taking more than the recommended dose may cause serious health problems. 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
■ 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 ■ TBSP = tablespoon ■ dose as follows
age | dose
adults and children 12 years of age and over | 30 mL (2 tablespoons) every 6 hours
children under 12 years of age | do not use
■ when using day time and night time products, carefully read each label to ensure correct dosing.
Other information
■ each (30 mL) contains: sodium 18 mg
■ store between 15-30°C (59-86°F) ■ do not refrigerate
Inactive ingredients
citric acid, FD&C yellow # 6, flavor, glycerin, honey, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose.
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 30 mL) Propósitos
Acetaminofén, 650 mg ..... Analgésico/Antifebril
Dextrometorfano HBr, 30 mg ..... Supresor de la tos
Succinato de Doxilamina 12.5 mg ..... Antihistamínico
Usos
■ alivia temporalmente los siguientes síntomas que se presentan con la gripe y el resfriado: ■ dolor de garganta ■ dolor de cabeza ■ dolores y molestias leves ■ secreción nasal y estornudo ■ tos ocacionada por irritación leve de garganta y bronquios
■ reduce temporalmente la fiebre.
Advertencias
Advertencia acerca del hígado: este producto contiene acetaminofén. Puede producirse daño hepático grave si toma: ■ más de 4 dósis (de 30 mL cada una) en 24 horas, que es la cantidad máxima diaria para 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 ■ enrojecimiento de la piel ■ ampollas ■ 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 severo, 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 medicamento que contenga acetaminofén (recetado o de venta libre). Si no está seguro si el medicamento contiene acetaminofén, preguntar a un médico
Información del Medicamento (continuación)
o farmacéutico ■ por más de 10 días para el dolor, excepto si es indicado por un doctor ■ por más de 3 días para la fiebre, excepto si es indicado por un doctor ■ si está tomando inhibidores de la monoamin oxidasa (IMAO) recetados (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 ■ para adormecer a un niño.
Consulte a su médico antes de usar si usted tiene
■ enfermedad hepática ■ glaucoma ■ tos que se presenta con demasiada flema (mucosidad) ■ problemas de respiración o tos crónica que persiste como sucede al fumar, con el asma, bronquitis crónica o enfisema ■ dificultad para orinar debido a agrandamiento de la próstata.
Consulte a su médico o farmacéutico antes de usarlo si
■ está tomando sedantes o tranquilizantes
■ está tomando el medicamento anticoagulante warfarina.
Al utilizar este producto
■ no usar más de lo indicado
■ evite bebidas alcohólicas
■ puede ocurrir excitabilidad, especialmente en niños
■ puede producirse somnolencia marcada
■ tenga cuidado al conducir un vehículo motorizado u operar maquinaria
■ el alcohol, los sedantes y los tranquilizantes pueden aumentar la somnolencia.
Suspenda su uso y consulte a su médico si ■ hay enrojecimiento o hinchazón ■ los síntomas no mejoran en 7 días o están acompañados de fiebre ■ la fiebre empeora o dura más de 3 días ■ se presentan nuevos síntomas ■ la tos dura más de 7 días, regresa u ocurre con fiebre, sarpullido o dolor de cabeza que permanece. Estos podrían ser signos de una afección grave.
Si está embarazada o lactando, consulte 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 puede provocar problemas de salud serios. En caso de sobredosis, buscar ayuda médica o comunicarse con un centro de toxicología de inmediato. La atención médica rápida es fundamental para adultos y niños, 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 ■ TBSP = cucharada ■ administrar dosis según se indica a continuación
edad | dosis
adultos y niños de 12 años de edad y mayores | 30 mL (2 cucharadas) cada 6 horas
niños menores de 12 años | no usar
■ cuando use productos de horario diurno y nocturno, lea cuidadosamente cada etiqueta para asegurar una dosificación correcta.
Otra información
■ cada (30 mL) contienen: 18 mg de sodio
■ almacenar entre 15 y 30 °C (59 a 86°F) ■ no refrigerar.
Ingredientes inactivos
ácido cítrico, FD&C amarillo 6, sabor, glicerina, miel, propilenglicol, agua purificada, benzoato de sodio solución de sorbitol, sacarosa.
¿Preguntas o comentarios? 1-877-994-3666
Lunes a Viernes de 8 am a 6 pm, Hora del Centro.
Genomma Lab.®
Distributed by / Distribuido por:
Genomma Lab USA Inc.,
Houston, TX 77098
Rev. 1
20000088986 V-2
6 50240 05124 1
BX-108
LOT No./LOTE:
EXP:

Night Time

Tukol ®
HONEY MULTISYMPTOM

COLD & FLU

Acetaminophen/ Dextromethorphan HBr /
Doxylamine succinate

Ages
12+

NATURAL

HONEY
FLAVOR

Relieves:
- HEADACHE, SORE THROAT, FEVER
- MINOR ACHES AND PAINS
- SNEEZING, RUNNY NOSE
- COUGH

4 FL OZ (118 ml)

TUKOL HONEY NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate syrup

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50066-303
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	21.667 mg in 1 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	1 mg in 1 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	0.4167 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HONEY (UNII: Y9H1V576FH)	
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:50066-303-04	1 in 1 CARTON	02/09/2020	
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 Drug	M012	02/09/2020	

Labeler - Genomma Lab USA (832323534)

Revised: 10/2024 Genomma Lab USA