

TUKOL MAXIUM STRENGTH COUGH AND MUCUS RELIEF - dextromethorphan hydrobromide, guaifenesin capsule, gelatin coated
Genomma Lab USA, Inc

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.

Drug Facts Active ingredients

Dextromethorphan HBr 10 mg
Guaifenesin 200 mg

Purpose

Cough Suppressant
Expectorant

Keep out of reach of children

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes
- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold

Warnings Do not use

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.

Ask a doctor before use if you have

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema

Stop use and ask a doctor if

cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding

ask a health professional before use.

Directions

- Do not take more than 12 softgels in any 24-hour period

- This product is not intended for use in children under 12 years
- Adults and children 12 years and over - 2 softgels every 4 hours
- Children under 12 years of age - do not use

Other information

- Store at room temperature
- Avoid excessive heat above 40° C (104° F)

Inactive ingredients

FD and C Red # 40, Gelatin, Glycerin, Polyethylene glycol, Povidone, Propylene glycol, Purified water, Sorbitol sorbitan solution, Titanium dioxide

Questions or comments?

1-877-99 GENOM (43666)

Tukol Maximum Strength Cough and Mucus Relief Label

Tukol®

Dextromethorphan HBr-Cough suppressant / Guaiifensin-Expectorant

Relieves

Cough

Mucus

Use in the morning, evening or anytime

MAIMUM STRENGTH

For ages 12 and over

20 SOFTGELS

Do not use if plastic blister is open or broken

Made in India

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

BX - 048

Información del Medicamento (continuación)

Información adicional

- almacene a temperatura ambiente
- evite el calor excesivo superior a 40 °C (104 °F)

Ingredientes inactivos

FDAC mg n° 40, Gomas, Glicerina, Povidona, Polietilenglicol, Agua purificada, Solución de sorbitol sorbitano, Dioxido de titanio

Questions or comments? / ¿Preguntas o comentarios?
1 877 99 GENOM (43666)

Do not use if plastic blister is open or broken / No lo utilice si el blister de plástico está abierto o roto!

Made in / Hecho en: India
Distributed by / Distribuido por:
Genomma Lab USA, Inc.
Houston, TX 77027
83-048



Tukol®

Dextromethorphan HBr-Cough suppressant/ Guaifenesin-Expectorant
Bromhidrato de dextrometorfano-Antitusivo/ Guaifenesina-Expectorante

Relieves / Alivia:

**Cough / Tos
Mucus / Mucosidad**

**Use in the morning,
evening or anytime**

**Utilícelo en la mañana, en la
noche o en cualquier momento**



**MAXIMUM STRENGTH
CONCENTRACION MAXIMA**

**For ages 12 and over
Para mayores de 12 años**



**20 SOFTGELS
CÁPSULAS BLANDAS**

**Relieves / Alivia:
Cough / Tos
Mucus / Mucosidad**

Tukol®

Dextromethorphan HBr-Cough suppressant/ Guaifenesin-Expectorant
Bromhidrato de dextrometorfano-Antitusivo/ Guaifenesina-Expectorante

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(per softgel)
Dextromethorphan HBr 10 mg... Cough Suppressant
Guaifenesin 200 mg... Expectorant

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Información del Medicamento

Ingredientes activos Propósito
(en cada cápsula blanda)
Bromhidrato de dextrometorfano 10 mg...Antitusivo
Guaifenesina 200 mg...Expectorante

Usos

- ayuda a aflojar la flegma (mucosidad) y a disminuir las secreciones bronquiales para drenar los bronquios
- alivia temporalmente la tos causada por irritación menor de la garganta y los bronquios que se produce con un resfriado

Advertencias

No utilícelo si usted está tomando un inhibidor de la monoamina oxidasa (IMAO) de prescripción (ciertos medicamentos para la depresión, condiciones psiquiátricas o emocionales, o enfermedades de Parkinson), o durante 2 semanas después de suspender el medicamento IMAO. Si usted desconoce si su medicamento de prescripción contiene un IMAO, consulte a su médico o farmacéutico antes de tomar este producto.

Consulte a un médico antes de utilizar el fármaco si usted tiene

- tos que se produce con demasiada flegma (mucosidad)
- tos duradera o crónica como la que se produce con tabaquismo, asma, bronquitis crónica o enfisema

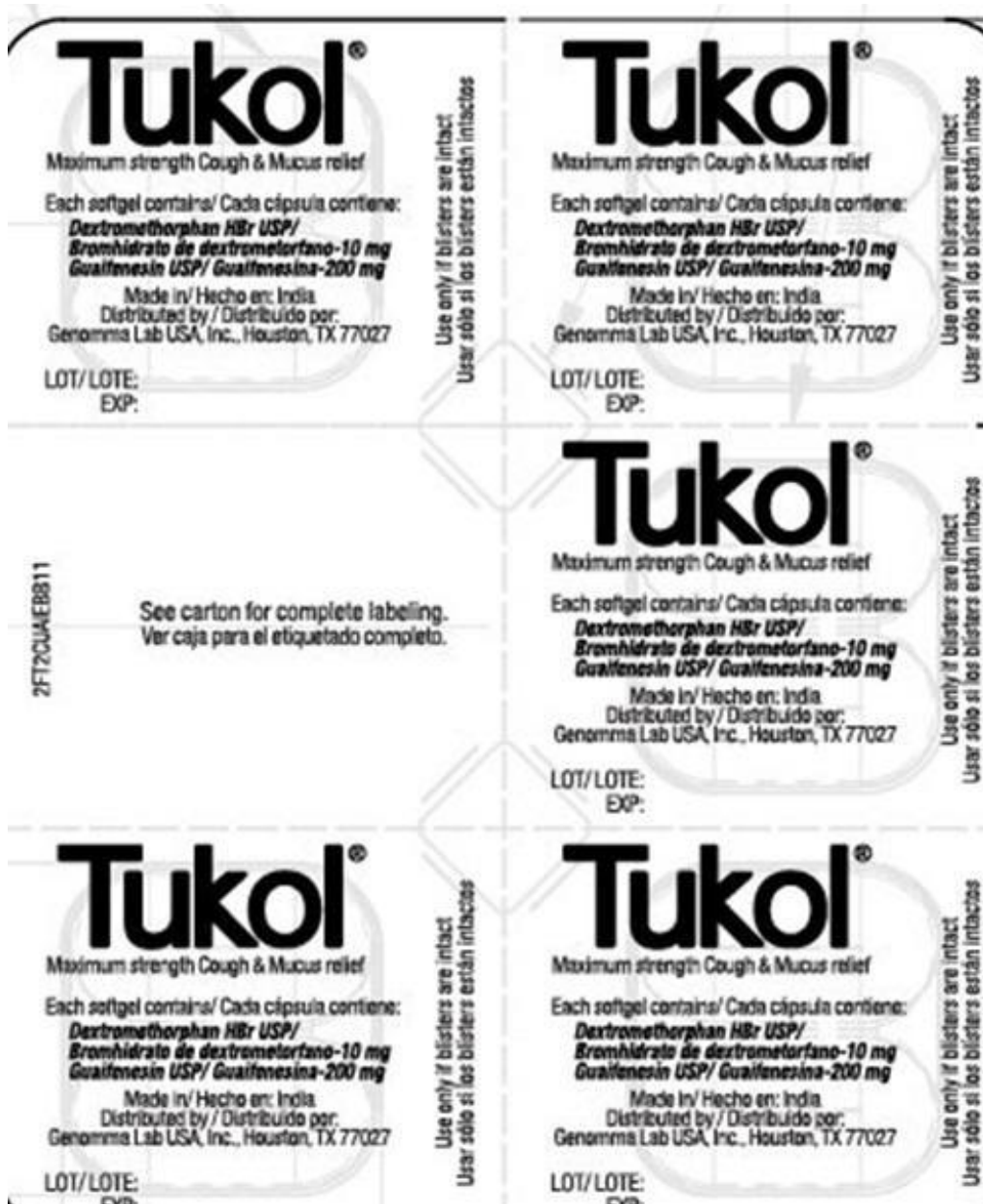
Suspenda su uso y consulte a un médico si la tos dura más de 7 días, regresa, o se acompaña de fiebre, erupción o dolor de cabeza persistente. Estos podrían ser signos de una afección grave.

En caso de embarazo o lactancia, consulte a un profesional de la salud antes de su uso.

Mantenga fuera del alcance de los niños. En caso de sobredosis, obtenga ayuda médica o contacte de inmediato a un Centro de Control de Intoxicación

Instrucciones de uso

- No tome más de 12 cápsulas blandas en un periodo de 24 horas
- Este producto no está previsto para su uso en niños menores de 12 años
- Adultos y niños mayores de 12 años- 2 cápsulas blandas cada 4 horas
- Niños menores de 12 años - no lo utilice



TUKOL MAXIUM STRENGTH COUGH AND MUCUS RELIEF

dextromethorphan hydrobromide, guaifenesin capsule, gelatin coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-601
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONES (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red (RED)	Score	no score
Shape	CAPSULE (OBLONG)	Size	20mm
Flavor		Imprint Code	601
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-601-02	20 in 1 CARTON		
1		1 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/17/2015	

Labeler - Genomma Lab USA, Inc (832323534)

Registrant - Aptapharma Inc (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
Aptapharma Inc		790523323	manufacture(50066-601) , relabel(50066-601) , repack(50066-601)