TUKOL MAX ACTION SINUS CAPLETS- acetaminophen, guaifenesin and phenylephrine hydrochloride tablet, coated 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 Caplets

Drug Facts

Active ingredients (in each caplet)	Purpose
Acetaminophen 325 mg	Pain reliever
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporarily relieves:
 - nasal congestion
 - headache
 - sinus congestion and pressure
 - minor aches and pains
- temporarily promotes nasal and/or sinus drainage
- 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 4,000 mg of acetaminophen in 24 hours
- 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:

- blisters
- rash
- skin reddening

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.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- heart disease
- diabetes
- thyroid disease
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- liver disease
- high blood pressure
- 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 exceed recommended dosage.

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- fever gets worse or lasts more than 3 days
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with 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

In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt 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 12 caplets in any 24-hour period
- adults and children 12 years and over: take 2 caplets every 4 hours
- children under 12 years: do not use

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, crospovidone, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions or comments?

Call 1-877-994-3666 8 AM-6 PM ET, Monday-Friday

Distributed by: **Genomma Lab USA Inc.**

Houston, TX, 77027

PRINCIPAL DISPLAY PANEL - 20 Caplet Blister Pack Carton

NEW

Tukol® MAX ACTION

SINUS

HEADACHE AND CONGESTION

Acetaminophen / Guaifenesin / Phenylephrine HCl Pain Reliever / Expectorant / Nasal Decongestant

- SINUS CONGESTION
- HEADACHE
- EXPECTORANT

Actual Size

20 Caplets

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Drug Facts (continued)

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Drug Facts (continued)

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NEW / NUEVO KO MAX ACTION

SINUS

HEADACHE AND CONGESTION

Acetaminophen / Guaifenesin / Phenylephrine HCI Pain Reliever / Expectorant / Nasal Decongestant

- SINUS CONGESTION / PRESIÓN DE LOS SENOS NASALES
- HEADACHE / DOLOR DE CABEZA
- EXPECTORANT / EXPECTORANTE

20 Caplets/Cápsulas

Actual Size / Tamaño Real

TUKOL MAX ACTION SINUS CAPLETS

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-306
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Acetaminophen (UNII: 36209ITL9D) (Acetaminophen - UNII:36209ITL9D)	Acetaminophen	325 mg	
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	200 mg	
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	Phenylephrine Hydrochloride	5 mg	

Inactive Ingredients		
Ingredient Name	Strength	
STARCH, CORN (UNII: O8232NY3SJ)		
crospovidone (UNII: 2S7830E561)		
magnesium stearate (UNII: 70097M6I30)		
maltodextrin (UNII: 7CVR7L4A2D)		
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)		
microcrystalline cellulose (UNII: OP1R32D61U)		

Product Characteristics				
Color	YELLOW	Score	no score	
Shape	OVAL	Size	7mm	
Flavor		Imprint Code	Т	
Contains				

P	Packaging					
#	Item Code	tem Code Package Description		Marketing End Date		
1	NDC:50066- 306-20	2 in 1 CARTON	03/20/2022			
1		10 in 1 BLISTER PACK; 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	03/20/2022	
TIVAL			

Revised: 3/2022 Genomma Lab USA