TUKOL NIGHT TIME COLD AND FLU RELIEF SOFTGELS- acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate capsule, liquid filled
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® Night Time Cold and Flu Relief Softgels

Drug Facts

Active ingredients **(in each softgel)**	***Purpose***
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 15 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine

Uses

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

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take
- more than 4 doses in 24 hours, which is the maximum daily amount
- 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 products 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 drugs. 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 sleep

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 enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

- do not exceed recommended dosage
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drink
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- pain or cough gets worse or lasts more than 7 days
- fever gets worse or last more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts
- a skin reaction occurs. 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. In case of accidental 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 directed (see Warnings)
- do not exceed 4 doses per 24 hours
  Adults and children 12 years and over: take 2 softgels with water every 6 hours
  Children 4 to under 12 years: Ask a doctor
  Children under 4 years: Do not use
- When using Day Time or Night Time products, carefully read each label to ensure correct dosing

Other information

- store at room temperature 20-25°C (68-77°F)

Inactive Ingredients

FD&C Blue #1, D&C Yellow #10, Gelatin, Glycerin, Polyethylene glycol, Povidone, Propylene glycol, Purified water, Sorbitol sorbitan solution, Titanium dioxide.

Questions or comments?

Call toll free **1-877-994-3666**

Weekdays from 8 am to 6 pm

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

PRINCIPAL DISPLAY PANEL - 24 Softgel Blister Pack Carton

NEW

Tukol®

NIGHT TIME
COLD AND FLU RELIEF

Acetaminophen / Dextromethorphan HBr /
Doxylamine succinate

- COUGH
- RUNNY NOSE
- SORE THROAT
- ACHES
- NASAL CONGESTION
- FEVER

24
Softgels

NIGHT TIME
COLD AND FLU RELIEF
ALIVIO DEL RESFRIADO Y GRIPE PARA LA NOCHE

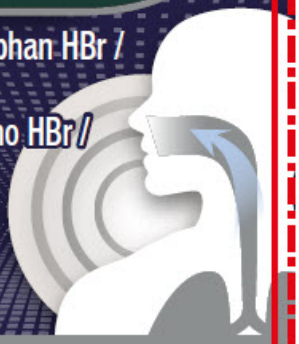
Tukol®

NEW / NUEVO

Tukol®

NIGHT TIME
COLD AND FLU RELIEF
ALIVIO DEL RESFRIADO Y GRIPE PARA LA NOCHE

Acetaminophen / Dextromethorphan HBr / Doxylamine succinate
Acetaminofén / Dextrometorfano HBr / Succinato de Doxilamina



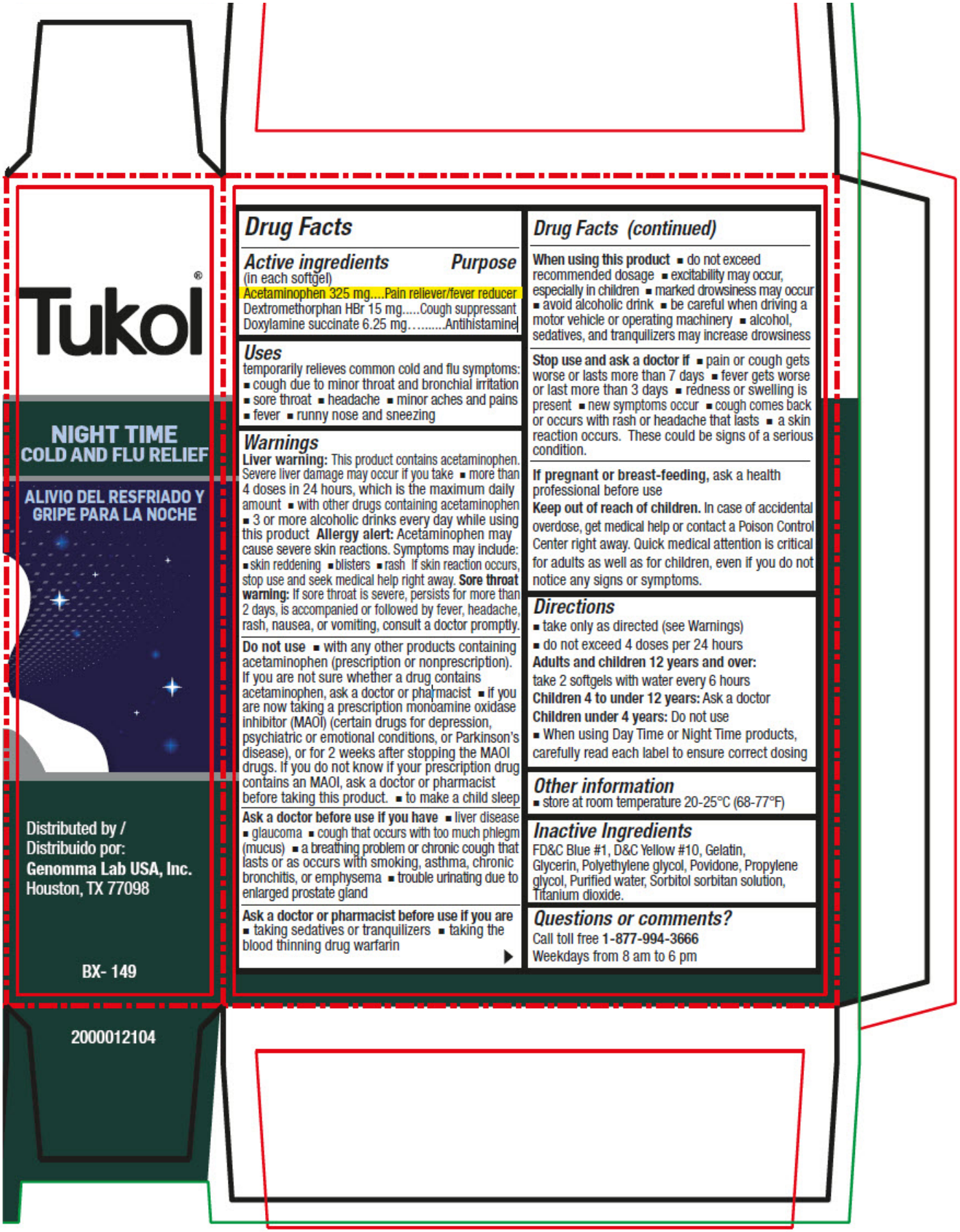
- **COUGH** / TOS
- **RUNNY NOSE** / FLUJO NASAL
- **SORE THROAT** / DOLOR DE GARGANTA
- **ACHES** / DOLOR
- **NASAL CONGESTION** / CONGESTION NASAL
- **FEVER** / FIEBRE

24 Softgels
Cápsulas blandas

Tamper Evident: Do not use if blisters are torn or open

Evidencia de Manipulación: No usar si los blisters están rotos o abiertos

6 50240 06481 4



TUKOL NIGHT TIME COLD AND FLU RELIEF SOFTGELS

acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50066-311
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	325 mg
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	15 mg
Doxylamine succinate (UNII: V9BI9B5YI2) (Doxylamine - UNII:95QB77JKPL)	Doxylamine succinate	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
gelatin, unspecified (UNII: 2G86QN327L)	
glycerin (UNII: PDC6A3C0OX)	
polyethylene glycol, unspecified (UNII: 3WQ0SDW1A)	
povidone, unspecified (UNII: FZ989GH94E)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	

Product Characteristics

Color	GREEN	**Score**	no score
Shape	OVAL	**Size**	11mm
Flavor		**Imprint Code**	603
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-311-24	2 in 1 CARTON	01/10/2023	
1		12 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	01/10/2023	

Labeler - Genomma Lab USA (832323534)

Revised: 1/2023

Genomma Lab USA