

TUKOL MAX ACTION- oxymetazoline hydrochloride liquid

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 Nasal Spray

Drug Facts

Active ingredient

Oxymetazoline HCl 0.05%

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to:
 - common cold
 - hay fever
 - upper respiratory allergies.
- Shrinks swollen nasal membranes so you can breathe more freely

Warnings

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland.

When using this product

- do not use more than directed
- do not use more than 3 days. Frequent or prolonged use may cause nasal congestion to recur or worsen.
- temporary discomfort such as burning, stinging, sneezing or an increase in nasal discharge may occur
- use of this container by more than one person may spread infection.

Stop use and ask a doctor if symptoms persist

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 6 to 12 years of age (with adult supervision): 2 or 3 sprays in each nostril not more than every 10 to 12 hours. Do not exceed 2 doses in any 24-hour period
- shake well before use. To spray, hold bottle with thumb at base and nozzle between first and second fingers. Without tilting head, insert nozzle into nostril. Fully depress rim with a firm, even stroke and sniff deeply. Wipe nozzle clean after use.
- **children under 6 years of age:** ask a doctor

Other information

- store between 20° and 25°C (68° and 77°F)
- keep carton for full labeling

Inactive ingredients

benzalkonium chloride, benzyl alcohol, edetate disodium, polyethylene glycol 1500, povidone K30, purified water, sodium phosphate dibasic, sodium phosphate monobasic monohydrate

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 - 15 ML Bottle Carton

NEW

Tukol®

MAX ACTION

NASAL SPRAY

Spray Nasal

Oxymetazoline HCl-Nasal Decongestant

Adults

12

Hour Relief

- FAST, POWERFUL
CONGESTION RELIEF

Pump Mist Anti-Drip

0.5 FL OZ (15ML)

Información del medicamento

Ingrediente activo Propósito

Oximetazolina.....Descongestionante
HCl 0.05% nasal

Usos ■ alivia temporalmente congestión nasal causados por:
■ resfriado común
■ fiebre alta
■ alergias en las vías respiratorias superiores
■ reduce inflamación de las mucosas nasales para que pueda respirar con mayor facilidad.

Advertencias

Consulte al médico antes de utilizar el producto si presenta

- enfermedad cardíaca
- presión arterial alta
- enfermedad tiroidea
- diabetes
- dificultad para orinar causada por dilatación de la próstata

Cuando utilice este producto

- no usar más de lo recomendado
- no lo use por más de 3 días. El uso frecuente o prolongado del producto puede provocar que la congestión nasal se repita o empeore
- molestia temporal como ardor, picazón, estornudo o incluso puede causar incremento en el escurrimiento nasal
- el uso de este dispensador por más de una persona puede propagar la infección.

Suspenda el uso del producto y consulte al médico si los síntomas persisten

Si está embarazada o en lactancia, antes de usar el producto consulte a un profesional médico. **Manténgase fuera del alcance de los niños.** En caso de ingesta, solicite asistencia médica o acuda de inmediato al Centro de Intoxicaciones.

Instrucciones

- adultos y niños de 6 a 12 años de

Oxymetazoline HCl-Nasal Decongestant /
Oximetazolina Descongestionante Nasal HCl

NASAL SPRAY
Spray Nasal

Tukol
MAX ACTION

Safety seal. Do not use if shrink wrap is broken or missing /
Sello de seguridad. No usar si la envoltura está rota o falta

NEW / NUEVO

Tukol[®]
MAX ACTION

NASAL SPRAY
Spray Nasal

Oxymetazoline HCl-Nasal Decongestant /
Oximetazolina Descongestionante Nasal HCl

Adults/
Adultos



● **FAST, POWERFUL
CONGESTION RELIEF**

● **RÁPIDO, PODEROSO**

edad (con supervisión adulta):
aplicar 2 o 3 aspersiones en cada fosa
nasal, no exceda el uso en un

ALIVIO A LA CONGESTIÓN

Pump Mist Anti-Drip

Bomba mist anti goteo 0.5 FL OZ (15ML)

Información del medicamento (continuación)

período de 10 a 12 horas. No exceda 2 dosis en un periodo dentro de 24 horas.

- agite el producto antes de usarlo. Para aplicar el spray, sostenga el envase colocando el pulgar en la base y la boquilla con el dedo índice y medio.

Sin inclinar la cabeza, coloque la boquilla del aplicador nasal dentro de la fosa nasal. Presione con un movimiento firme y parejo, e inhale profundamente. Lavar el limpiador nasal después de usarlo.

- Niños menores de 6 años de edad: consulte a su médico.

Información Adicional

- almacene el producto entre 20° C – 25° C (68° F – 77° F).
- conserve la etiqueta de la caja para futuras referencias

Ingredientes inactivos

cloruro de benzalkonio, alcohol de benzilo, desódico de edetato, polietilenglicol 1500, povidone K30, agua destilada, fosfato de sodio dibásico, fosfato de sodio monoháico dihidratado

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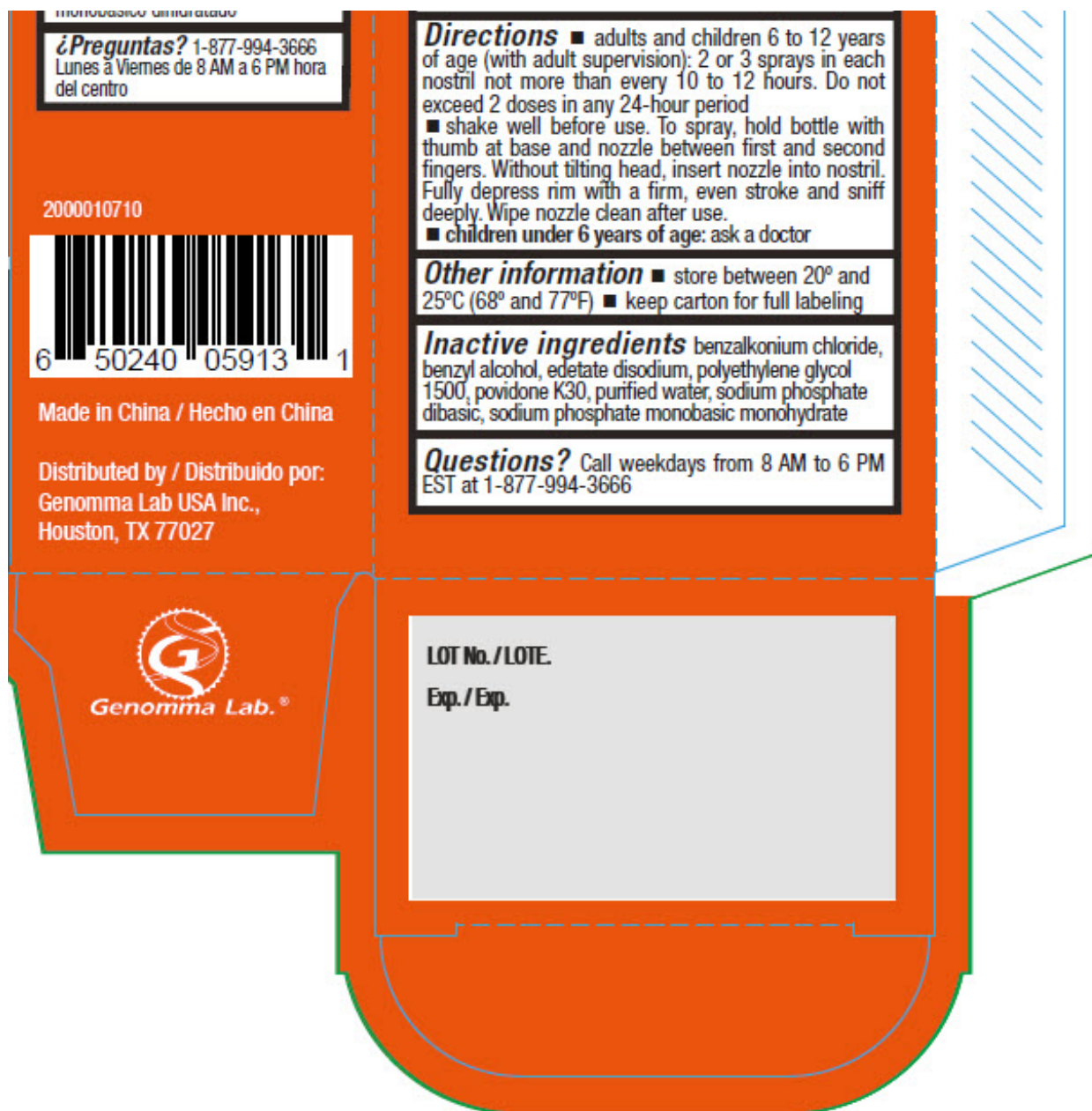
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TUKOL MAX ACTION

oxymetazoline hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-307
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
oxymetazoline hydrochloride (UNII: K89MJ0S5VY) (oxymetazoline - UNII:8VLN5B44ZY)	oxymetazoline hydrochloride	0.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
benzalkonium chloride (UNII: F5UM2KM3W7)	
Water (UNII: 059QF0KO0R)	
Benzyl alcohol (UNII: LKG8494WBH)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
Edetate disodium (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-307-05	1 in 1 CARTON	07/22/2021	
1		15 mL in 1 BOTTLE, SPRAY; 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	07/22/2021	

Labeler - Genomma Lab USA (832323534)

Revised: 7/2021

Genomma Lab USA