

T-RAOJO- tetrahydrozoline hydrochloride liquid
Promex, LLC

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 Ingredient

- Tetrahydrozoline HCl 0.5%

Purpose

- Redness reliever

Use

- for the relief of redness of the eye due to minor eye irritations

Warnings

Ask a doctor before use if you have narrow angle glaucoma

When using this product

- pupils may become enlarged temporarily
- overuse may cause more eye redness
- remove contact lenses before using
- do not use if this solution changes color or become cloudy
- do not touch tip of container to any surface to avoid contamination
- replace cap after each use

Stop use and ask a doctor if

- you feel eye pain
- changes in vision occur
- redness or irritation of the eye lasts
- condition worsens or lasts more than 72 hours

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

- Put 1 to 2 drops in the affected eye(s) up to 4 times daily
- children under 6 years of age: ask a doctor

Other information

- store between 15° to 25°C (59°F to 77°F)

Inactive ingredients

benzalkonium chloride, boric acid, edetate disodium, hydrochloric acid, purified water, sodium borate, sodium chloride

package label

Redness relief

T-Raajo
Colirio

• Tamper Evident. Do not use this product if neckband is missing or broken.

• Prueba de Manipulación. No utilice este producto si la banda del cuello falta o está roto.

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Tetrahydrozoline HCl 0.05%...Redness reliever

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Información del Medicamento

Ingrediente activo **Propósito**
Tetrahidrozolina HCl 0.05%.....Alivia Enrojecimiento

Uso ■ alivia el enrojecimiento de los ojos debido a irritaciones oculares menores

Precauciones
Consulte con un médico antes de usarlo si usted tiene glaucoma de ángulo estrecho

Al utilizar este producto
■ pupilas pueden agrandarse temporalmente
■ uso excesivo puede causar más enrojecimiento de los ojos

Drug Facts (continued)

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■ you feel eye pain
■ changes in vision occur
■ redness or irritation of the eye lasts
■ condition worsens or lasts more than 72 hours

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
■ put 1 to 2 drops in the affected eye(s) up to 4 times daily
■ children under 6 years of age: ask a doctor

Other information
■ store at 15 to 30°C (59 to 86°F)

Inactive ingredients
benzalkonium chloride, boric acid, edetate disodium, hydrochloric acid, purified water, sodium borate, and sodium chloride

Información del Medicamento (continuado)

■ quitar lentes de contacto antes de usar
■ No usar si la solución cambia de color o se enturbia
■ No toque la punta del envase con ninguna superficie para evitar la contaminación
■ tapar después de cada uso

Suspenda el uso y pregúntele al doctor si
■ siente dolor en los ojos
■ cambios en la visión ocurren
■ enrojecimiento o irritación de los ojos dura
■ condición empeora o perdura más de 72 horas

Si está embarazada o en periodo de lactancia, consulte a un profesional de la salud antes de usar.

Mantener fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o contactar con un centro de información toxicológica.

Indicaciones ■ Coloque 1 a 2 gotas en el ojo afectado hasta 4 veces al día ■ Menores de 6 años de edad: consulte un médico

Otra información guarde entre 15-30°C (59-86°F)

Ingredientes inactivos ácido bórico, ácido clorhídrico, agua, borato de sodio, cloruro de benzalconio, cloruro de sodio, edetato disódico

T-Raajo



Colirio
Alivio del Enrojecimiento

Eye Drops
Redness Reliever

Sterile / Estéril
0.5 fl. oz. (15mL)

Pro-Mex

PC-136.00

Distributed By: **Pro-Mex®**
Toll Free/Gratis: 1 (855) 977-6639 500 NE 190 St. Miami, FL 33179

Made in Korea / Fabricado en Corea



1 84125 00148 4

LOT: EXP:

T-Raajo
Colirio

Active ingredient: Tetrahydrozoline HCl 0.05%
WARNINGS: Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
DIRECTIONS: Put 1 to 2 drops in the affected eye(s) up to 4 times daily, children under 6 years of age, ask a doctor.
CAUTION: Do not use if the tamper-resistant bottle cap is broken or opened. **Inactive Ingredients:** See carton.
 Ingrediente activo: 0.05% HCl Tetrahydrozolina
ADVERTENCIAS: Mantener fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o póngase en contacto con un centro de toxicología de inmediato.
MODO DE EMPLEO: Poner 1-2 gotas en el ojo afectado (s) de hasta 4 veces al día.
 menores de 6 años de edad, consulte a un médico. **Ingresantes inactivos:** Ver carton.
PRECAUCIÓN: No utilice si la prueba de manipulaciones tapa de la botella se rompe o se abre.

READ CARTON FOR USES AND ALL WARNINGS
 LEA CARTON PARA USOS Y TODAS LAS ADVERTENCIAS

Redness Reliever Eye Drops
Colirio para aliviar enrojecimiento

0.5 fl. oz. (15mL) **LOT:**

Pro-Max®
 1 (855) 677-6638
 Miami, FL 33179
 Made in Korea /
 Fabricado en Corea

PC-135.00
 EXP:

T-RAOJO

tetrahydrozoline hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58988-0148
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TETRAHYDROZOLINE HYDROCHLORIDE (UNII: 0 YZT43HS7D) (TETRAHYDROZOLINE - UNII:S9U025Y077)	TETRAHYDROZOLINE HYDROCHLORIDE	0.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BORIC ACID (UNII: R57ZHV85D4)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0K00R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58988-0148-5	1 in 1 BOX		
1		15 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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Labeler - Promex, LLC (789974388)

Revised: 7/2014

Promex, LLC