TRIPROLIDINE HCL DROPS- triprolidine hcl drops liquid
Creekwood Pharmaceutical 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.

Triprolidine HCL Drops

Other information

Store at 59° - 86°F (15° - 30°C)

Warnings

Do not exceed recommended dosage.

Ask a doctor before use if the child has

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- diffculty in urination due to the enlargement of the prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

Do not use this product

- in a child who is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or are accompanies by fever

Keep out of reach of children.

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

Uses

Temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- Nasal Congestion
- reduces swelling of nasal passages
- runny nose

- sneezing
- itching of the nose or throat
- itchy,watery eyes

Drug Facts

Active ingredients

(in each 1 mL dropperful)

Triprolidine Hydrochloride 0.938mg

Purpose

Anitihistamine

Directions

Do Not exceed recommended dosage.

Use only with enclosed dropper. Do not use with any other device.

Adults and Children 12 years of age and over	2.67 mL every 4 hours to 6 hours,not to exceed 4 doses in 24 hours
Children 6 years to under 12 years of age:	1.33mL every 4 to 6 hours, not to exceed 4 doses in 24 hours
Children under 6 years of age:	Consult a doctor.

Inactive ingredients

Citric Acid, Cotton Candy Flavor, Glycerin, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol, Sucralose.

Questions Comments

Seek medical assistance immediately for serious side effects associated with the use of this product. Serious side effects may be reported to this number: 866-991-9870 (mon-Fri 8 a.m to 5 p.m EST)

Product Packaging

The packaging below represents the labeling currently used.

Principal display panel and side panel for 30 mL label:

NDC 15310-112-42
Triprolidine HCl Drops

Alllergic Rhintis, Respiratory Allergies & Nasal Decongestant
Common Cold

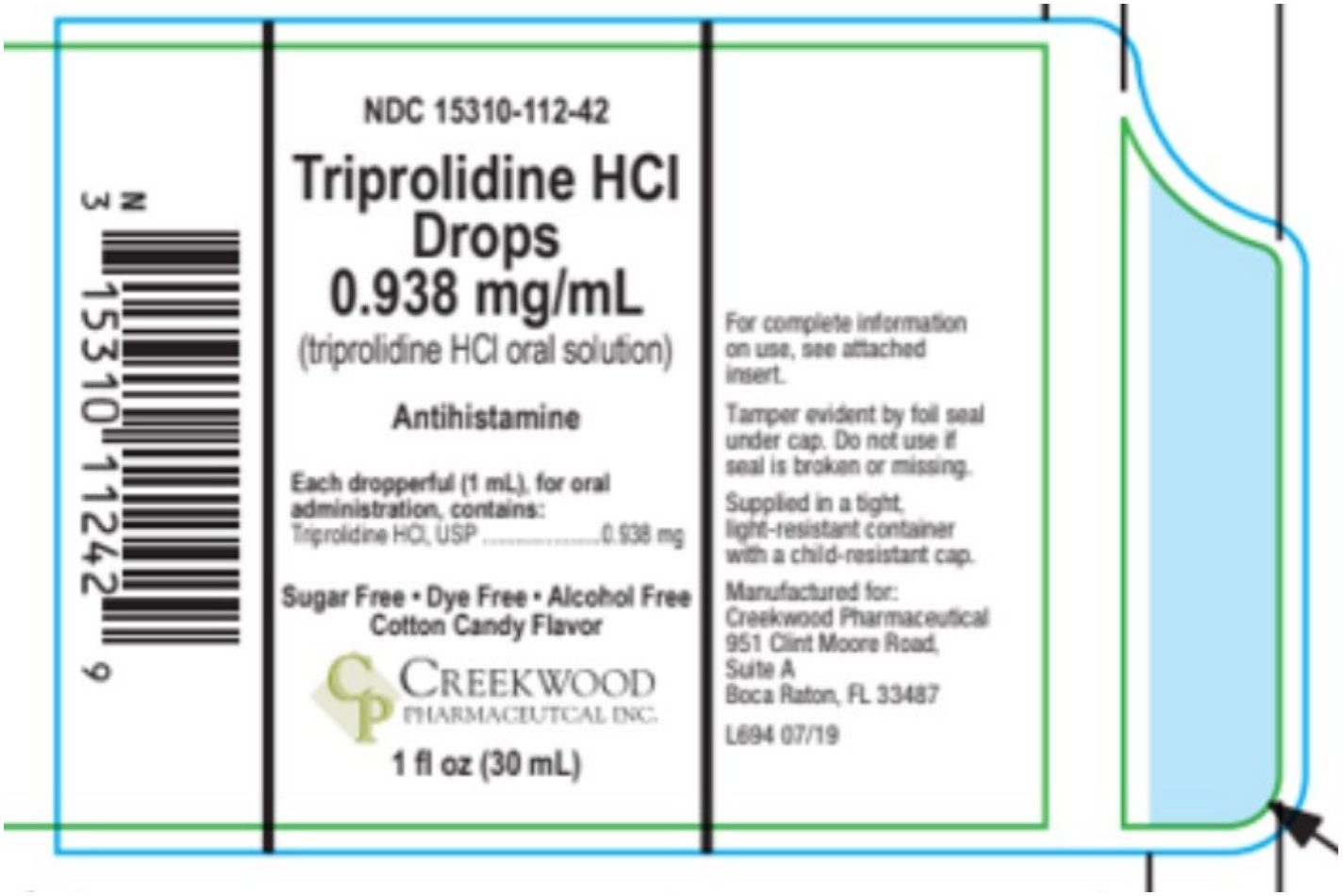
Alcohol-Free · Dye Free · Sugar Free · · Cotton Candy Flavor

Each Dropperful (1 mL) contains:
Triprolidine HCl, USP.....0.938 mg

Net Wt. 1 FL OZ (30 mL)

Tamper evident by foil seal under cap.
Do not use if foil seal is broken or missing.

Manufactured for:
Creekwood Pharmaceutical
951 Clint Moore Road,
Suite A
Boca Taton, FL 33487



TRIPROLIDINE HCL DROPS

triprolidine hcl drops liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:15310-112
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	0.938 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	COTTON CANDY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15310-112-42	1 in 1 BOX	12/06/2019	
1		30 mL in 1 BOTTLE; 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	12/06/2019	

Labeler - Creekwood Pharmaceutical Inc. (618997188)

Establishment

Name	Address	ID/FEI	Business Operations
Woodfield Pharmaceutical, LLC		079398730	manufacture(15310-112)

Revised: 11/2021 Creekwood Pharmaceutical Inc.