## HISTEX PD DROPS- triprolidine hydrochloride syrup Allegis Pharmaceuticals, 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.

-----

## HISTEX<sup>TM</sup> PD Drops

**Drug Facts** 

## Active ingredient (in each 1 mL dropperful)

Triprolidine HCl 0.938 mg

## Purpose

Antihistamine

#### Uses

temporarily relieves these symptoms due to hay fever (allergic rhinitis) or other upper respiratory allergies:

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

#### **Warnings**

Do not exceed recommended dosage.

#### Ask a doctor before use if the child has

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

## Ask a doctor before use if the child is taking sedatives or tranquilizers

## When using this product

- excitability may occur, especially in children
- may cause drowsiness
- sedatives and tranquilizers may increase the drowsiness effect

#### Stop use and ask a doctor if

new symptoms occur

#### Keep out of the reach of children.

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

#### **Directions**

#### Do not exceed recommended dosage.

• For dosing, use only the enclosed dropper and not with any other drug product.

AGE	DOSE
	2.67 mL (2.5 milligrams) every 4 to 6
Adults & Children 12 years of age	hours, not to exceed 10.67 mL (10
or older:	milligrams in 24 hours, or as directed by a
	doctor.
	1.33 mL (1.25 milligrams) every 4 to 6
Children 6 to under 12 years of	hours, not to exceed 5.33 mL (5
age:	milligrams in 24 hours, or as directed by a
-	doctor.
Children under 6 years of age:	Consult a doctor.

#### Other Information

Store at 15°-30° C (59°-86° F).

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

## **Inactive ingredients**

bubble gum flavor, citric acid, glycerin, methylparaben, monoammonium glycyrrhizinate, potassium citrate, potassium sorbate, propylene glycol, propylparaben, purified water, sucralose.

## **Questions? Comments?**

Call 1-866-633-9033.

### PRINCIPAL DISPLAY PANEL - 30 mL Bottle Label

NDC 28595-801-30

HISTEX™ PD

Drops

Antihistamine

Each dropperful (1 mL)

contains:

Triprolidine HCl 0.938 mg

Sugar-Free • Dye Free

Alcohol Free

**Bubble Gum Flavor** 

1 fl oz (30 mL)

Do not use if foil seal is missing or broken.

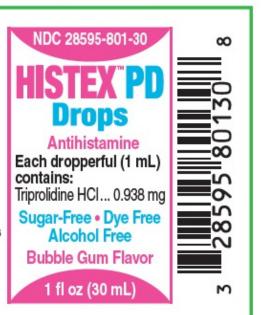
## Usual Dosage:

See attached labeling for complete product information. Store at 15°-30° C (59°-86° F).

## KEEP OUT OF REACH OF CHILDREN.

Manufactured for: Allegis Pharmaceuticals, LLC Canton, MS 39046

Rev. Date: 10/19





# Active ingredient Purpose (in each 1 mL dropperful)

Triprolidine HCl 0.938 mg ...... ...... Antihistamine

#### Uses

temporarily relieves these symptoms due to hay fever (allergic rhinitis) or other upper respiratory allergies:

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

## Warnings

Do not exceed recommended dosage.

## Ask a doctor before use if the child has

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

Ask a doctor before use if the child is taking sedatives or tranquilizers

#### When using this product

- excitability may occur, especially in children
- may cause drowsiness
- sedatives and tranquilizers may increase the drowsiness effect

#### Stop use and ask a doctor if

new symptoms occur

#### Keep out of the reach of children.

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

## **Drug Facts** (continued)

## Other Information

Store at 15°-30° C (59°-86° F).

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

## Inactive ingredients

bubble gum flavor, citric acid, glycerin, methylparaben, monoammonium glycyrrhizinate, potassium citrate, potassium sorbate, propylene glycol, propylparaben, purified water, sucralose.

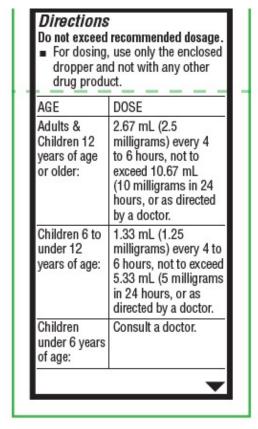
Questions? Comments? Call 1-866-633-9033.

#### Manufactured for:

Allegis Pharmaceuticals, LLC Canton, MS 39046

Rev. 10/19





### **HISTEX PD DROPS**

triprolidine hydrochloride syrup

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:28595-801
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TRIPRO LIDINE HYDRO CHLO RIDE (UNII: YAN7R5L890) (TRIPRO LIDINE - UNII: 2L8 T9 S52QM)	TRIPROLIDINE HYDROCHLORIDE	0.938 mg in 1 mL	

Strength

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
NDC:28595-801-30	1 in 1 CARTON	03/06/2014	
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	03/06/2014	

## **Labeler -** Allegis Pharmaceuticals, LLC (792272861)

Revised: 5/2020 Allegis Pharmaceuticals, LLC