

**PBZ OTC- tripeleannamine hcl 1% cream**  
**Kingsway Pharmaceuticals dba NFI, LLC**

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**PBZ™ OTC Cream**

**Active Ingredient**

Tripeleannamine HCL 1%

**Purpose**

Topical Analgesic

**Use**

**Temporarily relieves pain and itching associated with:**

- insect bites
- minor burns
- minor cuts
- minor skin irritations
- scrapes
- sunburn
- rashes due to poison ivy, poison oak, or poison sumac

**Warnings**

**For external use only.**

**Avoid contact with the eyes.**

**If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a physician.**

**Do not use**

**if packaging is damaged or opened.**

**If pregnant or breast-feeding,**

ask a health professional before use

**Keep out of reach of children and pets.**

If swallowed, get medical help or contact Poison Control Center right away.

**Directions**

**Adults and children 2 years of age and older:** Apply to affected area not more

than 3 to 4 times daily.

**Children under 2 years of age:** Do not use, consult a physician.

**Storage Information:** Protect from freezing and excessive heat, store at 68°-77°F (20°-25°C).

### **Inactive Ingredients**

Acrylates/Acrylamide Copolymer, Allantoin, Aloe Barbadensis Leaf Extract, Caprylic/Capric Triglyceride, Cetyl Alcohol, Dimethicone, dl-Alpha Tocopheryl Acetate, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Mineral Oil, Panthenol, PEG 100 Stearate, Phenoxyethanol, Polysorbate 80, Polysorbate 85, Sodium Polyacrylate, Stearic Acid, Triethanolamine, Water

### **MANUFACTURED IN THE USA**

#### **Distributed By:**

**Kingsway Pharmaceuticals dba NFI Consumer Products**

636 Shelby Street, Suite 300, Bristol, TN 37620

800-432-9334

### **PRINCIPAL DISPLAY PANEL - Carton Label**

#### **SAFE FOR THE ENTIRE FAMILY**

**pbz™**

OTC

**Pyribenzamine™**

NOW AVAILABLE OTC

#### **POWERFUL ITCH RELIEF**

ANTIHISTAMINE CREAM

AGES 2+ YRS

- ✓ Insect Bites
- ✓ Minor Burns, Cuts, Scrapes
- ✓ Minor Skin Irritations
- ✓ Poison Ivy, Oak, & Sumac
- ✓ Sunburn

ITCH

**Net WT 1 OZ. (28g)**



# pbz<sup>OTC</sup>

SAFE FOR THE ENTIRE FAMILY







**Drug Facts**

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Tripelemnamine HCL 1%      Topical Analgesic

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PBZ-PBD-24-002

**NOW AVAILABLE OTC**

POWERFUL  
ITCH RELIEF

**ANTIHISTAMINE CREAM**

**AGES 2+  
YRS**

3  
LESS  
THINGS  
TO WORRY  
ABOUT:

- ✓ Safe to use with oral diphenhydramine
- ✓ Fewer side effects compared to hydrocortisone
- ✓ Safe for children ages 2 and older

- ✓ Insect Bites
- ✓ Minor Burns, Cuts, Scrapes
- ✓ Minor Skin Irritations
- ✓ Poison Ivy, Oak, & Sumac
- ✓ Sunburn



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## PBZ OTC

tripelennamine hcl 1% cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69993-151
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TRIPLENNAMINE</b> (UNII: 3C5ORO99TY) (TRIPLENNAMINE - UNII:3C5ORO99TY)	TRIPLENNAMINE	1 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>DIMETHICONE, UNSPECIFIED</b> (UNII: 92RU3N3Y10)	
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>PANTHENOL</b> (UNII: WW9CM0O67Z)	
<b>PEG-100 MONOSTEARATE</b> (UNII: YD01N1999R)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POLYSORBATE 85</b> (UNII: A7F3N56197)	
<b>SODIUM POLYACRYLATE (8000 MW)</b> (UNII: 285CYO341L)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69993-151-01	1 in 1 CARTON	02/01/2025	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	02/01/2025	

**Labeler** - Kingsway Pharmaceuticals dba NFI, LLC (121681919)

Revised: 1/2025

Kingsway Pharmaceuticals dba NFI, LLC